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BOOK 2:
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Book 2 of 2 Books
Friday, October 31, 1980

72404 Part II—HHS/FDA:
Certain Biological Products and Human Blood and Blood Products; Changes in Proper Names, Proposed Labeling Requirements and Reorganization and Revision of Regulations

72430 Part III—Labor/ESA:
Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

72464 Part IV—OFR:
Incorporation by Reference; Approvals, Extensions, and Corrections

72465 Part V—Interior/OSMRE:
Partial Approval/Disapproval of the Permanent Program Submission From the State of Illinois Under the Surface Mining Control and Reclamation Act of 1977

72508 Part VI— Interior/ HCRS:
1981 Action Program—Identification of Nationwide Recreation Issues

72512 Part VII—HHS/PHS:
Health Maintenance Organizations; Employees' Health Benefits Plans

72524 Part VIII—HHS/PHS:
Requirements for a Health Maintenance Organization

72538 Part IX—HHS/HCFA:
Medicare Program; Qualifying Conditions and Reimbursement of Health Care Prepayment Plans

72552 Part X—DOE/ERA:
Domestic Crude Oil Entitlements

72582 Part XI—HHS/FDA:
Therapeutically Equivalent Drugs; Availability of List

72610 Part XII—EEOC:
Guidelines on Discrimination Because of Religion

federal register

Friday
October 31, 1980

Part II

Department of Health and Human Services

Food and Drug Administration

Certain Biological Products; Changes in Proper Names, and Human Blood and Blood Products; Proposed Labeling Requirements and Reorganization and Revision of Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 600, 606, 610, 620, 630, 640, 660

[Docket No. 80N-0053]

Changes in Proper Names of certain Biological Products

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) proposes to amend the biological regulations by: (1) Changing the proper names for certain biological products, (2) updating all applicable regulations in Part 600 et seq. to reflect these new names, and (3) updating and reorganizing § 610.53(a) (21 CFR 610.53(a)) for clarity. The proper names are being changed to reduce the length of the name, more accurately identify the product, and eliminate many inconsistencies between the United States Pharmacopeia (USP) and the biologics regulations.

DATE: Comments by December 30, 1980. FDA proposes that any final regulation issued under this proposal be effective 180 days after the date of publication of the final regulation for products initially introduced or initially delivered for introduction into interstate commerce. For blood and blood components, however, FDA proposes that the effective date be 1 year after publication of a final regulation issued under the proposed uniform blood labeling regulation published elsewhere in this issue of the **Federal Register.**

ADDRESS: Written comments to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, Pike, Bethesda MD 20857.

FOR FURTHER INFORMATION CONTACT: Paul Hiranaka, Bureau of Biologics (HFB-620), Food and Drug Administration, 8800 Rockville, MD 20205, 301-443-1306.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration (FDA) is proposing to amend the biologics regulations by: (1) Changing the proper names of certain biological products, (2) updating all applicable regulations in Parts 600 through 660 to reflect these new names, and (3) updating and reorganizing § 610.53(a) (21 CFR 610.53(a)) for clarity. The agency has been cooperating with the United States Adopted Names Council (USAN) to improve the proper names of many biological products. USAN is sponsored by the American Medical Association, the United States Pharmacopeial Convention (USP), and the American Pharmaceutical Association. USAN assigns nonproprietary names to new drugs as they are developed, establishes principles for designating names, and conducts a continuing review of product names to ensure that the names concisely and accurately identify specific products. Suitable nonproprietary names serve important functions because they properly identify the substances to which they apply, facilitate better communication between physicians and other professionals, and may be used without restriction by the public at large, as opposed to restrictions imposed upon the use of trademark names. The names that USAN develops or accepts from other agencies are likely to achieve worldwide recognition.

Name Change Amendments

FDA considered changes in the proper names of biological products to more accurately identify the product, to shorten the proper names, if appropriate, and to eliminate inconsistencies between names for products found in the USP and the biologics regulations. Consistent with USAN principles for designating meaningful and distinctive nonproprietary names, FDA proposes to amend the biologics regulations to change the proper names of certain blood products, viral products, bacterial products, antivenins, and allergenic extracts, as follows:

Proposed name	Present name
Blood Products	
1. Albumin	Normal Serum Albumin (Human)
2. Antihemophilic Factor	Antihemophilic Factor (Human)
3. Cryoprecipitated AHF	Cryoprecipitated Antihemophilic Factor (Human)
4. Factor IX Complex	Factor IX Complex (Human)
5. Fibrinolysin	Fibrinolysin (Human)
6. Immune Globulin	Immune Serum Globulin (Human)
7. Mumps Immune Globulin	Mumps Immune Globulin (Human)
8. Measles Immune Globulin.	Measles Immune Globulin (Human)
9. Pertussis Immune Globulin.	Pertussis Immune Globulin (Human)
10. Plasma	Single Donor Plasma (Human)
11. Plasma Fresh Frozen	Single Donor Plasma (Human), Fresh Frozen
12. Plasma Liquid	Single Donor Plasma (Human), Liquid
13. Plasma Platelet Rich	Single Donor Plasma (Human), Platelet Rich
14. Plasma Protein Fraction	Plasma Protein Fraction (Human)
15. Platelets	Platelet Concentrate (Human)
16. Rabies Immune Globulin.	Rabies Immune Globulin (Human)
17. Reagent Red Blood Cells.	Reagent Red Blood Cells (Human)
18. Red Blood Cells	Red Blood Cells (Human)
19. Red Blood Cells Deglycerolized.	Red Blood Cells (Human), Deglycerolized
20. Red Blood Cells Frozen	Red Blood Cells (Human), Frozen
21. Rho(D) Immune Globulin.	Rho(D) Immune Globulin (Human)
22. Source Plasma	Source Plasma (Human)
23. Source Plasma Liquid	Source Plasma (Human), Liquid
24. Source Plasma Pooled	Source Plasma (Human), Pooled
25. Source Plasma Salvaged.	Source Plasma (Human), Salvaged
26. Tetanus Immune Globulin.	Tetanus Immune Globulin (Human)
27. Vaccinia Immune Globulin.	Vaccinia Immune Globulin (Human)
28. Whole Blood	Whole Blood (Human)
29. Whole Blood Platelets and/or Cryoprecipitate Removed.	Whole Blood (Human), Modified
Viral Products	
1. Measles Virus Vaccine Live.	Measles Virus Vaccine, Live Attenuated
2. Measles, Mumps and Rubella Virus Vaccine Live.	Measles, Mumps, and Rubella Virus Vaccine, Live
3. Measles and Rubella Virus Vaccine Live.	Measles and Rubella Virus Vaccine, Live
4. Measles-Smallpox Vaccine Live.	Measles-Smallpox Vaccine, Live
5. Mumps Virus Vaccine Live.	Mumps Virus Vaccine, Live
6. Poliovirus Vaccine Live Oral, Trivalent.	Poliovirus Vaccine Live, Oral, Trivalent
7. Poliovirus Vaccine Live Oral, Type I.	Poliovirus Vaccine Live, Oral, Type I
8. Poliovirus Vaccine Live Oral, Type II.	Poliovirus Vaccine Live, Oral, Type II
9. Poliovirus Vaccine Live Oral, Type III.	Poliovirus Vaccine Live, Oral, Type III
10. Poliovirus Vaccine Inactivated.	Poliomyelitis Vaccine
11. Rubella and Mumps Virus Vaccine Live.	Rubella and Mumps Virus Vaccine, Live
12. Rubella Virus Vaccine Live.	Rubella Virus Vaccine, Live
13. Adenovirus and Influenza Virus Vaccines Combined Adsorbed.	Adenovirus and Influenza Virus Vaccines Combined Aluminum Phosphate Adsorbed
Bacterial Products	
1. Anthrax Vaccine Adsorbed.	Anthrax Vaccine, Adsorbed
2. Diphtheria and Tetanus Toxoids and Pertussis and Poliovirus Vaccines Inactivated, Adsorbed.	Diphtheria and Tetanus Toxoids and Pertussis and Poliomyelitis Vaccines Adsorbed
3. Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed and Poliovirus Vaccine Inactivated.	Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed and Poliomyelitis Vaccine
4. Tetanus and Diphtheria Toxoids Adsorbed for Adult Use.	Tetanus and Diphtheria Toxoids Adsorbed (For Adult Use)
Antivenins	
1. Antivenin Rattlesnake, Copperhead and Moccasin.	Antivenin (Crotolidae) Polyvalent
2. Antivenin Widow Spider	Antivenin (Lactrodectus mactans)
3. Antivenin Coral Snake	Antivenin (Micrurus fulvius)
Allergenic Extracts	
Allergenic Extracts Adsorbed.	Allergenic Extractrs, Alum Precipitated

FDA is proposing amendments in the proper names to:

1. Delete the word "Human" from the name of blood products intended for human use because all of these products are now derived from human sources. In the past, certain blood products were derived from bovine as well as human sources. Since there is no longer any reason to distinguish between sources, and because the products are recognized

by the medical community as originating from humans, the word "Human" may now be deleted from the proper name of the products.

2. Delete the words "Normal" and "Serum" from the proper name of Normal Serum Albumin (Human). The term "Normal" is confusing because it may be interpreted incorrectly to mean that serum albumin may also be produced from abnormal serum. The word "Serum" is being deleted because, during the last 28 years, the albumin has been derived primarily from plasma (serum plus the blood clotting elements), with a very small percentage of albumin being derived from plasma of the placental origin.

3. Change the proper name of Cryoprecipitated Antihemophilic Factor (Human) to Cryoprecipitated AHF because it will reduce the length of the name. The revised name will clearly distinguish this product (a blood component of Single Donor Plasma prepared in the blood bank) from Antihemophilic Factor (a blood derivative prepared by fractionation from pools of human plasma).

4. Delete the term "Concentrate" from the proper name of Platelet Concentrate. The word "Concentrate" used in the proper name is derived from the method of platelet collection, which involves separation from the plasma and concentration by additional centrifugation. Because this concentration procedure is the usual method of processing, however, FDA believes that the deletion of the term "Concentrate" will not confuse the identity of the product. This proposed proper name change would be consistent with the proper name of the product Red Blood Cells which is not called a concentrate, even though it consists of the red cell portion of blood.

5. Delete the words "Single Donor" from the proper name of Single Donor Plasma (Human), which is plasma primarily intended for intravenous injection. The types of single donor plasma, such as platelet rich or fresh frozen, shall be designated by the proper descriptive modifier following the proper name, e.g., Plasma Platelet Rich. Similarly, varieties of Source Plasma (plasma which is intended for further manufacturing) shall be designated by the proper descriptive modifier following the name, e.g., Source Plasma Liquid.

6. Revise the proper names for Whole Blood (Human) and Red Blood Cells (Human), by preceding the proper name with the name of the specific anticoagulant used. For example, Whole Blood (Human) and Red Blood Cells (Human), collected in anticoagulant citrate phosphate dextrose (CPD) solution shall be called CPD Whole Blood and CPD Red Blood Cells, respectively.

7. Revise the proper name Whole Blood (Human) Modified, to Whole Blood Platelets and/or Cryoprecipitate Removed, in order to more accurately identify the product. The proper name shall be preceded by the name of the anticoagulant used.

8. Change the proper name of Poliomyelitis Vaccine to Poliovirus Vaccine Inactivated to be consistent with the nomenclature of other viral vaccines which indicate the name of the virus producing the vaccine, rather than the name of the disease. As a result of this proposed change, the proper name of the mixed vaccines containing Poliomyelitis Vaccine would be changed accordingly. (See the listing of proper name changes of Bacterial Products.)

9. Delete the word "Attenuated" from the proper name of Measles Virus Vaccine, Live, Attenuated, to make it consistent with the proposed proper names of other live virus vaccines, such as Poliovirus Vaccine Live Oral, Mumps Virus Vaccine Live, or Rubella Virus Vaccine Live.

10. Change the proper name of Adenovirus and Influenza Virus Vaccines Combined Aluminum Phosphate Adsorbed to Adenovirus and Influenza Virus Vaccines Combined Adsorbed; and Allergenic Extracts, Alum Precipitated to Allergenic Extracts Adsorbed. The names of these two products are being changed to be consistent with the names of other adsorbed products which do not contain the name of the adsorbing agent.

11. Revise the proper names for licensed antivenin products. The proposed name changes for the three licensed antivenins follow a uniform format and provide a method for naming future Antivenin products. The proper name Antivenin is followed by the common name of the animal or group of animals producing the venom, but does not include the taxonomic genus and species name. The common name identifies the product and is, therefore, more easily recognized by untrained personnel or others who may need to use the product. The word Antivenin precedes the common names so that all the Antivenins may be properly alphabetized and readily found in any index on antivenins.

Under current license requirements, the package label for each antivenin must include its animal source. In addition, the package insert must include the taxonomic genus and species of the animal or group of animals producing the venom. The package insert must also identify and include the taxonomic genus and species of the animal or animals against whose venom the product is effective and those for which the product is known or suspected to be ineffective.

Miscellaneous Amendments

FDA is also proposing miscellaneous amendments to:

12. Delete commas from the proper names of most biological products, unless the product name contains three or more separate entities and use of a comma is grammatically correct. Removing the commas from the names of most products will not affect their specific identification and will provide a consistent guideline for naming future products. However, commas will continue to be used in proper names when they are needed for clarification.

13. Delete in § 610.53 the 10–year dating period for Normal Serum Albumin (Human), when the product is packaged is hermetically sealed metal containers, because Normal Serum Albumin (Human) is no longer being packaged in such containers. Therefore, a specified dating period is not needed for this kind of packaging.

14. Delete in § 610.53 certain products and their dating periods because they are no longer licensed, and to codify existing dating periods for licensed products which have not been previously listed for which data establish that period beyond which the product cannot be expected beyond reasonable doubt to yield its specific results and retain its safety, purity, and potency. The appropriate data to support these dating periods are on file with the Dockets Management Branch.

The following products would be deleted from the list in § 610.53:

(1) Adenovirus and Influenza Virus Vaccines Combined Aluminum Hydroxide Adsorbed.

(2) Aggregated Radio-Iodinated (I^{131}) Albumin (Human).

(3) Anti-Human Chorionic Gonadotropic Serum.

(4) Blood Grouping Serum Anti-Xg [a].

(5) Cobra Venom Solution.

(6) Cobra Venom Solution with Silicic and Formic Acids.

(7) Diphtheria and Tetanus Toxoids and Poliomyelitis Vaccine.

(8) Diphtheria Toxoid and Pertussis Vaccine.

(9) Fibrinogen (Human).

(10) Fibrinogen with Antihemophilic Factor (Human).

(11) Diphtheria Toxoid and Pertussis Vaccine Adsorbed.

(12) Gas Gangrene Polyvalent Antitoxin.

(13) Haemophilus Influenzae Typing Serum.
(14) Histamine Azoprotein.
(15) Lymphogranuloma Venereum Antigen.
(16) Modified Plasma (Bovine).
(17) Mumps Vaccine.
(18) Poliomyelitis Vaccine Adsorbed.
(19) Polyvalent modified bacterial antigens with "No U.S. Standard of Potency."
(20) Pseudomonas Polysaccharide.
(21) Radio-Chromated (Cr^{51}) Serum Albumin (Human).
(22) Radio-Iodinated (I^{125}) Serum Albumin (Human).
(23) Radio-Iodinated (I^{131}) Serum Albumin (Human).
(24) Reagent Blood Group Specific Substances A and B.
(25) Rocky Mountain Spotted Fever Vaccine.
(26) Russell Viper Venom.
(27) Schick Test Control.
(28) Staphylococcus Antitoxin.
(29) Tetanus and Gas Gangrene Polyvalent Antitoxin.
(30) Trichinella Extract.

The following products would be added to the list in § 610.53:
(1) Anti-Carcinoembryonic Antigen Serum.
(2) Asparaginase.
(3) Blood Grouping Serum Anti-Co^b.
(4) Hepatitis B Immune Globulin.
(5) Meningococcal Polysaccharide Vaccine Group A.
(6) Meningococcal Polysaccharide Vaccine Group C.
(7) Meningococcal Polysaccharide Vaccine Group A and C Combined.
(8) Pertussis Vaccine Adsorbed.
(9) Pneumococcal Vaccine Polyvalent.
(10) Rabies Immune Globulin.
(11) Red Blood Cells Deglycerolized.

15. Update the dating period for freeze-dried Allergenic Products in § 610.53 to reflect the minimum dating period currently approved as part of a manufacturer's license application. The minimum dating period for such products will be 4 years from the date of manufacture.

16. Change the heading or § 610.53 from "Dating periods for specific products," to "Dating periods for biological products." The dating periods prescribed in § 610.53 apply to general types of bioloical products, rather than to the manufacturer's brand of each product. "Specific product" can be misinterpreted to mean the manufacturer's brand.

17. Change in § 610.53 the dating period for Tuberculin, Purified Protein Derivative, diluted (used for the Mantoux test) to 6 months, based on stability data submitted to the agency. The stability data are on file with the Dockets Management Branch.

18. Revise and reorganize § 610.53 to facilitate interpretation by clearly identifying the dating periods during and after manufacturer's storage and revoke §§ 610.51 and 610.52. As a result of the revision of § 610.53, §§ 610.51 and 610.52 will no longer be necessary.

To permit manufacturers sufficient time to comply with the requirements of any final regulation issued under this proposal the agency proposes that the effective date of the final regulation, except for blood and blood components, be 180 days after the date of its publication in the **Federal Register** for biological products initially introduced or initially delivered for introduction into interstate commerce. For blood and blood components, FDA proposes that the effective date be 1 year after publication of a final regulation issued under the proposed uniform blood labeling regulation published elsewhere in this issue of the **Federal Register.**

The agency has determined under 21 CFR 25.24(d)(10) (proposed December 11, 1979; 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 501, 502, 510, 701, 52 Stat. 1040–1042 as amended, 1049–1051 as amended, 1055–1056 as amended, 76 Stat. 794–795 as amended (21 U.S.C. 321, 351, 352, 360, and 371); the Public Health Service Act (secs. 351, 351, 353, and 361, 58 Stat. 702 and 703 as amended, 81 Stat. 536 (42 U.S.C. 262, 263, 263a, 264)), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Chapter I of Title 21 of the Code of Federal Regulations be amended as follows:

PART 600—BIOLOGICAL PRODUCTS: GENERAL

A. In Part 600:

§ 600.13 [Amended]

1. In § 600.13 by changing the proper names "Whole Blood (Human); Cryoprecipated Antihemophilic Factor (Human); Platelet Concentrate (Human); Red Blood Cells (Human); Single Donor Plasma (Human); and Source Plasma (Human)" to read "Whole Blood; Cryoprecipitated AHF; Platelets; Red Blood Cells; Plasma; and Source Plasma".

2. In § 600.15 by revising paragraph (a), to read as follows:

§ 600.15 Temperatures during shipment.

The following products shall be maintained during shipment at the specified temperatures:

(a) *Products.*

Product	Temperature
Cryoprecipitated AHF	−18° C or colder.
Measles, Mumps and Rubella Virus Vaccine Live.	10° C or colder.
Measles and Rubella Virus Vaccine Live.	Do.
Measles-Smallpox Vaccine Live.	Do.
Measles Virus Vaccine Live	Do.
Mumps Virus Vaccine Live	Do.
Platelets	Between 1° and 10° C if suspended in 20 to 30 mL of plasma or all reasonable methods to maintain the temperature as close as possible to a range between 20° to 24° C, if suspended in 30 to 50mL of plasma.
Plasma	−18° C or colder.
Plasma Fresh Frozen	Do.
Plasma Liquid	1° to 10° C.
Plasma Platelet Rich	Between 1° and 10° C or all reasonable methods to maintain the temperature as close as possible to a range between 20° and 24° C.
Poliovirus Vaccine Live Oral, Trivalent.	0° C or colder.
Poliovirus Vaccine Live Oral, Type I.	Do.
Poliovirus Vaccine Live Oral, Type II.	Do.
Poliovirus Vaccine Live Oral, Type III.	Do.
Red Blood Cells Frozen	−65° C or colder.
Red Blood Cells (liquid product).	Between 1° and 10° C.
Rubella and Mumps Virus Vaccine Live.	10° or colder.
Rubella Virus Vaccine Live	Do.
Smallpox Vaccine (liquid product).	0° C or colder.
Source Plasma	−5° C or colder.
Source Plasma Liquid	10° C or colder.
Whole Blood	Between 1° and 10° C.
Yellow Fever Vaccine	0° C or colder.

* * * * *

PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

§ 606.120 [Amended]

B. In Part 606 by revising the heading and by amending § 606.120 in paragraph (b)(2) by changing the proper name "Source Plasma (human)" to read "Source Plasma", and in paragraph (b)(9) by changing the proper names "Cryoprecipitated Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF", and "Source Plasma (Human)" to read "Source Plasma".

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

C. In Part 610:

§ 610.11 [Amended]

1. In § 610.11(g) by changing the proper names "Whole Blood (Human);

Red Blood Cells (Human); Cryoprecipitated Antihemophilic Factor (Human); Platelet Concentrate (Human); and Single Donor Plasma (Human)" to read "Whole Blood; Red Blood Cells; Cryoprecipitated AHF; Platelets; and Plasma".

§ 610.12 [Amended]

2. In § 610.12(g)(4) by changing the proper names, "Whole Blood (Human); Cryoprecipitated Antihemophilic Factor (Human); Platelet Concentrate (Human); Red Blood Cells (Human); Single Donor Plasma (Human); and Source Plasma (Human)" to read "Whole Blood; Cryoprecipitated AHF; Platelets; Red Blood Cells; Plasma; and Source Plasma," and in paragraph (g)(7) by changing the proper names "Normal Serum Albumin (Human) and Plasma Protein Fraction (Human)" to read "Albumin and Plasma Protein Fraction"; and by deleting reference to Fibrinogen (Human).

§ 610.13 [Amended]

3. In § 610.13(a)(2)(ii) by changing the proper names, "Measles Virus Vaccine, Live, Attenuated; Measles-Smallpox Vaccine, Live; Rubella Virus Vaccine, Live; and Antihemophilic Factor (Human)" to read "Measles Virus Vaccine Live; Measles-Smallpox Vaccine Live; Rubella Virus Vaccine Live; and Antihemophilic Factor"; in paragraph (a)(2)(iii) by deleting the reference to Modified Plasma (Bovine) and Fibrinogen (Human); in the introductory text of paragraph (b) by changing the proper names, "Cryoprecipitated Antihemophilic Factor (Human); Single Donor Plasma (Human); and Source Plasma (Human)" to read "Cryoprecipitated AHF; Plasma; and Source Plasma"; in paragraph (b)(1)(i) by deleting the phrase "and at least 30 milligrams for Fibrinogen (Human)"; and in paragraph (b)(1)(ii) by deleting the names "Aggregated Radio-Iodinated (I^{131}) Albumin (Human); Radio-Chromated (Cr^{151}) Serum Albumin (Human); Radio-iodinated (I^{125}) Serum Albumin (Human); and Radio-Iodinated (I^{131}) Serum Albumin (Human)".

§ 610.15 [Amended]

4. In § 610.15(a) by changing the proper name "Poliovirus Vaccine, Live, Oral" to read "Poliovirus Vaccine Live Oral".

§ 610.51 [Deleted]

5. By deleting § 610.51 *Periods of cold storage.*

§ 610.52 [Deleted]

6. By deleting § 610.52 *Dating period.*

7. By revising § 610.53, to read as follows:

§ 610.53 Dating periods for licensed biological products.

(a) *General.* The following dating periods are based on data relating to usage, clinical experience, or laboratory tests that establish the period beyond which the product cannot be expected beyond resonable doubt to yield its specific results and retain its safety, purity, and potency, provided the product is maintained at the recommended temperatures. The standards prescribed by the regulations in this subchapter, designed to ensure continued safety, purity, and potency of the products, are based on the dating periods set forth below, and package labels shall recommend storage at the appropriate temperatures.

(b) *When the dating period begins.* The dating period for a product shall begin on the date of manufacture, as prescribed in § 610.50. The dating period for a combination of two or more products shall be no longer than the dating period of the component with the shortest dating period.

(c) *Table of dating periods.* In using the following table, a product in column A may be stored by the manufacturer at the prescribed temperature and length of time in either column B or C, plus the length of time in column D. The dating period in column D shall be applied from the day the product leaves the manufacturer's storage, provided the product has not exceeded its maximum storage period, as prescribed in column B or C. If a product is held in the manufacturer's cold storage beyond the period prescribed, the dating period shall be reduced by a corresponding period.

A Product	B Manufacturer's storage period 1°–5° C (unless otherwise stated)	C Manufacturer's storage period 0° C or colder (unless otherwise stated)	D Dating period after leaving manufacturer's storage 2°–8° C (unless otherwise stated)
Adenovirus and influenza virus vaccines combined adsorbed.	Six months	Not applicable	Six months.
Adenovirus vaccine	Six months	do	Six months.
Albumin	Three years	do	(a) Five years, provided labeling recommends storage between 2° and 10° C, or (b) Three years, provided labeling recommends storage at room temperature, no warmer than 37° C.
Allergenic extracts:			
1. With 50 percent or more glycerin.	Three years	do	Three years.
2. With less than 50 percent glycerin.	Eighteen months	do	Eighteen months.
3. Products for which cold storage conditions are inappropriate.	Not applicable	do	Eighteen months (from date of manufacture), provided labeling recommends storage at 30° C or colder.
4. Powders and tablets	Not applicable	do	Five years (from date of manufacture), provided labeling recommends storage at 30° C or colder.
5. Freeze-dried products:			
a. Unreconstituted	do	do	Four years (from date of manufacture).
b. Reconstituted	do	do	Eighteen months (cannot exceed 5 year unreconstituted dating period).
Allergenic extracts adsorbed	Eighteen months	do	Eighteen months.
Anthrax vaccine adsorbed	Two years	do	One year.
Antibody to hepatitis B surface antigen.	Six months	do	Six months.
Iodinated (125_I)	Not applicable	do	Forty-five days (from date of manufacture).
Anti-carcinoembryonic antigen serum.	do	do	One year (from date of manufacture) at 4°–8° C.

A Product	B Manufacturer's storage period 1°–5° C (unless otherwise stated)	C Manufacturer's storage period 0° C or colder (unless otherwise stated)	D Dating period after leaving manufacturer's storage 2°–8° C (unless otherwise stated)
Antihemophilic factor	do	do	One year (from date of manufacture).
Anti-human serum:			
1. Liquid	One year	Two years	One year.
2. Dried	do	do	Five years.
Antirabies serum	do	do	Two years.
Antivenom coral snake	do	do	Five years with an initial 10 percent excess of potency.
Antivenom rattlesnake, copperhead and moccasin	do	do	Five years with an initial 10 percent excess of potency, provided labeling recommends storage at 37° C or colder.
Antivenom widow spider	do	do	Five years with an initial 10 percent excess of potency.
Asparaginase	Not applicable	do	Eighteen months from the date of the last valid potency test.
BCG vaccine	One year	Not applicable	Six months.
Blood grouping serums—Anti-A:			
1. Liquid	One year	Two years	One year.
2. Dried	do	do	Five years.
Anti-A [1]	do	do	One year.
Anti-A, B:			
1. Liquid	do	do	One year.
2. Dried	do	do	Five years.
Anti-B:			
1. Liquid	do	do	One year.
2. Dried	do	do	Five years.
Anti-C:			
1. Liquid	do	do	One year.
2. Dried	do	do	Five years.
Anti-c	do	do	One year.
Anti-CD:			
1. Liquid	do	do	One year.
2. Dried	do	do	Five years.
Anti-CDE	do	do	One year.
Anti-C [2]	do	do	One year.
Anti-Co [3]	do	do	One year.
Anti-D:			
1. Liquid	do	do	One year.
2. Dried	do	do	Five years.
Anti-DE	do	do	One year.
Anti-Di [4]	do	do	One year.
Anti-E:			
1. Liquid	do	do	One year.
2. Dried	do	do	Five years.
Anti-e	do	do	One year.
Anti-Fy [5]	do	do	One year.
Anti-Fy [6]	do	do	One year.
Anti-I	do	do	One year.
Anti-Jk [7]	do	do	One year.
Anti-Jk [8]	do	do	One year.
Anti-Js [9]	do	do	One year.
Anti-K	do	do	One year.
Anti-k	do	do	One year.
Anti-Kp [10]	do	do	One year.
Anti-Kp [11]	do	do	One year.
Anti-Le [12]:			
1. Liquid	do	do	One year.
2. Dried	do	do	Five years.
Anti-Le [13]:			
1. Liquid	do	do	One year.
2. Dried	do	do	Five years.
Anti-M	do	do	One year.
Anti-M [14]	do	do	One year.
Anti-N	do	do	One year.
Anti-P [15]	do	do	One year.
Anti-S	do	do	One year.
Anti-s:			
1. Liquid	do	do	One year.
2. Dried	do	do	Five years.
Anti-U	do	do	One year.
Blood group substance AB	do	do	Two years.
Blood group substance A	do	do	Two years.
Blood group substance B	do	do	Two years.
Botulism antitoxin	do	do	Five years with an initial 20 percent excess of potency.
Cholera vaccine	do	Not Applicable	Eighteen months.
Coccidiodin	do	do	Three years.
Collagenase	Not applicable	do	Four years (from date of manufacture) provided labeling recommends storage at 37° C or colder.
Cryoprecipitated AHF	do	do	Twelve months from the date of collection of source blood, provided labeling recommends storage at 18° C or colder.

A Product	B Manufacturer's storage period 1°–5° C (unless otherwise stated)	C Manufacturer's storage period 0° C or colder (unless otherwise stated)	D Dating period after leaving manufacturer's storage 2°–8° C (unless otherwise stated)
Diphtheria antitoxin:			
1. Liquid	One year	Two years	Five years with an initial 20 percent excess of potency.
2. Dried	do	do	Five years with an initial 10 percent excess of potency.
Diphtheria and tetanus toxoids and pertussis and poliovirus vaccines inactivated, adsorbed.	Two months	Not applicable	Four months.
Diphtheria and tetanus toxoids and pertussis vaccine adsorbed and poliovirus vaccine inactivated:			
1. If all components are mixed when issued.	Two months	do	Four months.
2. If the pertussis and poliovirus components are unmixed when issued.	One year	do	One year.
Diphtheria and tetanus toxoids and pertussis vaccine.	One year	do	Eighteen months.
Diphtheria and tetanus toxoids and pertussis vaccine adsorbed.	do	do	Eighteen months.
Diphtheria and tetanus toxoids	do	do	Two years.
Diphtheria and tetanus toxoids adsorbed.	do	do	Two years.
Diphtheria toxin for Schick test	do	do	One year.
Diphtheria toxoid	do	do	Two years.
Diphtheria toxoid adsorbed	do	do	Two years.
Factor IX complex	Not applicable	do	One year (from date of manufacture).
Fibrinolysin	One year	Two years	Two years.
Fibrinolysin and desoxyribonuclease combined (bovine).	do	do	Three years, provided labeling recommends storage at 30° C or colder.
Fibrinolysin and desoxyribonuclease combined (bovine) with chloramphenicol.	do	do	Three years, provided labeling recommends storage at 30° C or colder.
Hepatitis B immune globulin	Not applicable	Not applicable	One year.
Hepatitis B surface antigen	Six months	do	Six months.
1. Unlyophilized coated red blood cells.	Not applicable	do	Fourteen days (from date of manufacture).
2. Iodinated (125_I) product	do	do	Forty-five days (from date of manufacture).
Histoplasmin	One year	do	Two years.
Immune globulin	Three years	do	Three years.
Influenza virus vaccine	One year	do	Eighteen months.
Leukocyte typing serum (dried)	Not applicable	Not applicable	Two years (from date of manufacture).
Anti-HL-A 1	do	do	Do.
Anti-HL-A 2	do	do	Do.
Anti-HL-A 3	do	do	Do.
Anti-HL-A 5	do	do	Do.
Anti-HL-A 7	do	do	Do.
Anti-HL-A 8	do	do	Do.
Anti-HL-A 9	do	do	Do.
Anti-HL-A 10	do	do	Do.
Anti-HL-A 11	do	do	Do.
Anti-HL-A 12	do	do	Do.
Anti-HL-A 13	do	do	Do.
Limulus amebocyte lysate	Not applicable	Not applicable	Eighteen months (from date of manufacture).
Measles, mumps and rubella virus vaccine live.	do	One year (−20° C or colder).	One year.
Measles and mumps virus vaccine live.	do	One year (−20° C or colder).	One year.
Measles and rubella virus vaccine live.	do	One year (−20° C or colder).	One year.
Measles immune globulin	Three years	Not applicable	Three years.
Measles-smallpox vaccine live	Not applicable	do	One year (from date of manufacture).
Measles virus vaccine live	do	One year (−20° C or colder).	One year.
Meningococcal polysaccharide vaccine group A:			
1. Final bulk powder	do	Eighteen months (−20° C or colder).	Not applicable.
2. Final container	Not applicable	Not applicable	Six months (−20° C or colder).
Meningococcal polysaccharide vaccine group C:			
1. Final bulk powder	do	Eighteen months (−20° C or colder).	Not applicable.
2. Final container	do	Not applicable	Six months.
Meningococcal polysaccaride vaccine groups A and C combined.	do	do	Six months (−20° C or colder)
Mumps immune globulin	Three years	do	Three years (from date the dried or frozen bulk product is placed in final solution).
Mumps skin test antigen	One year	do	Eighteen months.

A Product	B Manufacturer's storage period 1°–5° C (unless otherwise stated)	C Manufacturer's storage period 0° C or colder (unless otherwise stated)	D Dating period after leaving manufacturer's storage 2°–8° C (unless otherwise stated)
Mumps virus vaccine live	Not applicable	One year (−20° C or colder).	One year.
Normal horse serum	One year	Two years	Five years.
Pertussis immune globulin	Three years	Not applicable	Three years from date the dried or frozen bulk product is placed in final solution.
Pertussis vaccine	One Year	do	Eighteen months.
Pertussis vaccine adsorbed	do	do	Eighteen months.
Plague vaccine	do	do	Eighteen months.
Plasma	Not applicable	do	Five years from date of collection of source blood (−16° C or colder).
Plasma fresh frozen	do	do	One year from date of collecton of source blood (−16° C or colder).
Plasma liquid	do	do	(a) Twenty-six days from date of collection of source blood. (b) 40 days from the date collection of source blood only when CPDA–1 solution is used as the anticoagulant (between 1° and 6° C).
Plasma platelet rich	do	do	Seventy-two hours from time of collection of source blood (20° to 24° C or between 1° and 6° C).
Plasma protein fraction	One year	do	(a) Five years. (b) Three years (provided labeling recommends storage at 30° C or colder).
Platelets	Not applicable	do	Seventy-two hours from time of collection of source blood, provided labeling recommends storage at 20°–24° C or between 1° to 6° C.
Pneumococcal vaccine polyvalent:			
1. Final bulk powder	do	Fifteen months after potency assay (−20° C or colder).	Not applicable.
2. Final container	do	Not applicable	Two years (after date of manufacture).
Poliovirus Vaccine inactivated	One year	do	One year.
Poliovirus vaccine live oral, trivalent:			
1. Frozen	Not applicable	One year (−10° C or colder).	One year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state.
2. Liquid	do	Not applicable	Thirty days, provided labeling recommends storage between 2° and 8° C and container has been unopened.
Poliovirus vaccine live oral, type I:			
1. Frozen	do	One year (−10° C or colder).	One year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state.
2. Liquid	do	Not applicable	Thirty days, provided labeling recommends storage between 2° and 8° C and container has been unopened.
Poliovirus vaccine live oral, type II:			
1. Frozen	do	One year (−10° C or colder).	One year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state.
2. Liquid	do	Not applicable	Thirty days, provided labeling recommends storage between 2° and 8° C and container has been unopened.
Poliovirus vaccine live oral, type III:			
1. Frozen	do	One year (−10° C or colder).	One year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state.
2. Liquid	do	Not applicable	Thirty days, provided labeling recommends storage between 2° and 8° C and container has been unopened.
Polyvalent bacterial antigens with "No U.S. standard of potency":			
1. Liquid	One year	Not applicable	Eighteen months.

A	B	C	D
Product	Manufacturer's storage period 1°–5° C (unless otherwise stated)	Manufacturer's storage period 6° C or colder (unless otherwise stated)	Dating period after leaving manufacturer's storage 2°–8° C (unless otherwise stated)
2. Dried	....do	....do	Five years.
Polyvalent bacterial vaccines with "No U.S. standard of potency":			
1. Liquid	One year	....do	Eighteen months.
2. Dried	....do	....do	Five years.
Rabies immune globulin	One year	Not applicable	One year.
Rabies vaccine:			
1. Dried	One year	Two years	Eighteen months.
2. Liquid	Three months	Not applicable	Six months.
Reagent red blood cells	Not applicable	....do	Thirty-five days from earliest date of collection.
ACD red blood cells	....do	....do	(a) Twenty-one days from date of collection of source blood provided labeling recommends storage between 1° and 6° C and the hermetic seal is not broken during processing. (b) Twenty-four hours after plasma removal, provided labeling recommends storage between 1° and 6° C, if the hermetic seal is broken during processing.
CPD red blood cells	....do	....do	(a) Twenty-one days from date of collection of source blood provided labeling recommends storage between 1° and 6° C and the hermetic seal is not broken during processing. (b) Twenty-four hours after plasma removal, provided labeling recommends storage between 1° and 6° C, if the hermetic seal is broken during processing.
CPDA–1 red blood cells	....do	....do	(a) Thirty-five days from date of collection of source blood provided labeling recommends storage between 1° and 6° C and the hermetic seal is not broken during processing. (b) Twenty-four hours after plasma removal, provided labeling recommends storage between 1° and 6° C, if the hermetic seal is broken during processing.
Red blood cells deglycerolized	....do	....do	Twenty-four hours after removal from storage at −65° C or colder provided labeling recommends storage between 1° and 6° C.
Red blood cells frozen	....do	....do	Three years from date of collection of source blood, provided labeling recommends storage at −65° C or colder.
$Rh_o(D)$ immune globulin	Six months	....do	Six months.
Rubella and mumps virus vaccine live.	Not applicable	One year (−20° C or colder).	One year.
Rubella virus vaccine live	Not applicable	One year (−20° C or colder).	One year.
Smallpox vaccine:			
1. Liquid	Not applicable	Nine months (=10° C or colder), if product is maintained as glycerinated or equivalent vaccine in bulk or final containers.	Three months, provided labeling recommends storage at 0° C, or colder.
2. Dried	Six months	Not applicable	Eighteen months.
Source plasma	Not applicable	....do	In lieu of an expiration date the collection date shall appear on the label as prescribed in § 640.70(a)(6) of this chapter.
Staphylococcus toxoid	One year	....do	Two years.
Streptokinase	....do	Two years	Eighteen months.
Streptokinase-streptodornase:			
1. Dried	....do	Not applicable	Two years.
2. Tablets	Six months	....do	Eighteen months provided labeling recommends storage at 30° C or colder.
Tetanus and diphtheria toxoids adsorbed for adult use.	One year	....do	Two years.
Tetanus antitoxin:			
1. Liquid	....do	Two years	Five years with an initial 20 percent excess of potency.

A Product	B Manufacturer's storage period 1°–5° C (unless otherwise stated)	C Manufacturer's storage period 0° C or colder (unless otherwise stated)	D Dating period after leaving manufacturer's storage 2°–8° C (unless otherwise stated)
2. Dried	....do	....do	Five years with an initial 10 percent excess of potency.
Tetanus immune globulin	....do	Not applicable	Three years with an initial 10 percent excess of potency.
Tetanus toxoid	....do	....do	Two years.
Tetanus toxoid adsorbed	....do	....do	Two years.
Thrombin	....do	Two years	Three years.
Tuberculin:			
1. Purified protein derivative, concentrated containing at least 50 percent glycerin.	One year	Not applicable	Two years.
2. Purified protein derivative, diluted.	Six months	....do	One year.
3. Old or purified protein derivative, dried on multiple puncture device.	One year (not to exceed 30° C. Do not refrigerate.	....do	Two years, provided labeling recommends storage at a temperature not to exceed 30° C. Do not refrigerate.
Typhoid vaccine	One year	....do	Eighteen months.
Typhus vaccine	One year	....do	Eighteen months.
Vaccinia immune globulin	Three years	....do	Three years.
ACD whole blood	Not applicable	....do	Twenty-one days from date of collection, provided labeling recommends storage between 1° and 6° C.
CPD whole blood	....do	....do	Twenty-one days from date of collection, provided labeling recommends storage between 1° and 6° C.
CPDA–1 whole blood	....do	....do	Thirty-five days from date of collection, provided labeling recommends storage between 1° and 6° C.
Heparin whole blood	....do	....do	Forty-eight hours from date of collection, provided labeling recommends storage between 1° and 6° C.
Yellow fever vaccine	....do	One year (−20° or colder)	One year, provided labeling recommends storage at 5° C or colder.

(d) *Exemptions.* Exemptions or modifications shall be made only upon written approval, in the form of an amendment of the product license, issued by the Director, Bureau of Biologics.

PART 620—ADDITIONAL STANDARDS FOR BACTERIAL PRODUCTS

D. In Part 620:

§ 620.4 [Amended]

1. In § 620.4(g) by changing the proper name "Poliomyelitis Vaccine" to read "Poliovirus Vaccine Inactivated".

Subpart C—[Heading Amended]

§ 620.20 [Amended]

2. In the heading of Subpart C and the heading and text of § 620.20 by changing the proper name "Anthrax Vaccine, Adsorbed" to read "Anthrax Vaccine Adsorbed."

PART 630—ADDITIONAL STANDARDS FOR VIRAL VACCINES

Subpart A—[Heading Amended]

E. In Part 630:

1. In the heading of Subpart A by changing the proper name "Poliomyelitis Vaccine" to read "Poliovirus Vaccine Inactivated."

§ 630.1 [Amended]

2. In the heading of § 630.1 and in the text of paragraphs (a) and (c) by changing the proper name "poliomyelitis Vaccine" to read "Poliovirus Vaccine Inactivated."

§ 630.2 [Amended]

3. In the heading of § 630.2 and in paragraph (e)(3) by changing the proper name "Poliomyelitis Vaccine" to read "Poliovirus Vaccine Inactivated."

§ 630.3 [Amended]

4. In the introductory paragraphy of § 630.3 by changing the words "poliomyelitis vaccine" to read "poliovirus vaccine".

§ 630.4 [Amended]

5. In § 630.4(b)(1), by changing the words "poliomyelitis vaccine" to read "poliovirus vaccine" and in paragraph (e)(5)(ii) by changing the word "poliomyelitis" to read "poliovirus."

§ 630.6 [Amended]

6. In § 630.6 by changing the proper name "Poliomyelitis Vaccine" to read "Poliovirus Vacine Inactivated."

Subpart B—[Heading Amended]

7. In the heading of Subpart B by changing the proper name "Poliovirus

Vaccine, Live, Oral" to read "Poliovirus Vaccine Live Oral."

§ 630.10 [Amended]

8. In the heading of § 630.10 and in paragraphs (a) and (b)(2) by changing the proper name "Poliovirus Vaccine, Live, Oral" to read "Poliovirus Vaccine Live Oral."

§ 630.12 [Amended]

9. In § 630.12(a)(1) and (b) by changing the proper name "Poliovirus Vaccine, Live, Oral" to read "Poliovirus Vaccine Live Oral."

§ 630.13 [Amended]

10. In the heading of § 630.13 by changing the proper name "Poliovirus Vaccine, Live, Oral" to read "Poliovirus Vaccine Live Oral."

§ 630.18 [Amended]

11. In § 630.18 by changing the proper name "Poliovirus Vaccine, Live, Oral" to read "Poliovirus Vaccine Live Oral."

Subpart D—[Heading Amended]

12. In the heading of Subpart D by changing the proper name "Measles Virus Vaccine, Live, Attenuated" to read "Measles Virus Vaccine Live."

§ 630.30 [Amended]

13. In the heading of § 630.30 and in paragraphs (a) and (b)(2) by changing the proper name "Measles Virus Vaccine, Live, Attenuated" to read "Measles Virus Vaccine Live."

§ 630.36 [Amended]

14. In § 630.36(d) by changing the proper name "measles Virus Vaccine, Live, Attenuated" to read "Measles Virus Vaccine Live."

§ 630.37 [Amended]

15. In § 630.37 by changing the proper name "Measles Virus Vaccine, Live, Attenuated" to read "Measles Virus Vaccine Live."

Subpart F—[Heading Amended]

16. In the heading of Subpart F by changing the proper name "Mumps Virus Vaccine, Live" to read "Mumps Virus Vaccine Live."

§ 630.50 [Amended]

17. In the heading of § 630.50 and in paragraphs (a) and (b)(2) by changing the proper name "Mumps Virus Vaccine, Live" to read "Mumps Virus Vaccine Live."

§ 630.51 [Amended]

18. In § 630.51 by changing the proper name "Mumps Virus Vaccine, Live" to read "Mumps Virus Vaccine Live."

§ 630.52 [Amended]

19. In the heading of § 630.52 by changing the proper name "Mumps Virus Vaccine, Live" to read "Mumps Virus Vaccine Live."

§ 630.56 [Amended]

20. In § 630.56(b) and (e) by changing the proper name "Mumps Virus Vaccine, Live" to read "Mumps Virus Vaccine Live."

§ 630.57 [Amended]

21. In § 630.57 by changing the proper name "Mumps Virus Vaccine, Live" to read "Mumps Virus Vaccine Live."

Subpart G—[Heading Amended]

22. In the heading of Subpart G by changing the proper name "Rubella Virus Vacine, Live" to read "Rubella Virus Vaccine Live."

§ 630.60 [Amended]

23. In the heading of § 630.60 and in paragraphs (a) and (d) by changing the proper name "Rubella Virus Vaccine, Live" to read "Rubella Virus Vaccine Live."

§ 630.61 [Amended]

24. In § 630.61 by changing the proper name "Rubella Virus Vaccine, Live" to read "Rubella Virus Vaccine Live."

§ 630.62 [Amended]

25. In § 630.62(b) by changing the proper name "Rubella Virus Vaccine, Live" to read "Rubella Virus Vaccine Live."

§ 630.66 [Amended]

26. In § 630.66 (b) and (d) by changing the proper name "Rubella Virus Vaccine, Live" to read "Rubella Virus Vaccine Live."

§ 630.67 [Amended]

27. In § 630.67 by changing the proper name "Rubella Virus Vaccine, Live" to read "Rubella Virus Vaccine Live."

Subpart I—[Heading Amended]

28. In the heading of Subpart I by changing the proper name "Measles-Smallpox Vaccine, Live" to read "Measles-Smallpox Vaccine Live."

§ 630.80 [Amended]

29. In the heading of § 630.80 and in paragraph (a) by changing the proper name "Measles-Smallpox Vaccine, Live" to read "Measles-Smallpox Vaccine Live."

§ 630.84 [Amended]

30. In the introductory paragraph of § 630.84 by changing the proper name "Measles-Smallpox Vaccine, Live" to read "Measles-Smallpox Vaccine Live."

§ 630.87 [Amended]

31. In § 630.87 by changing the proper name "Measles-Smallpox Vaccine, Live" to read "Measles-Smallpox Vaccine Live."

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

F. In Part 640:

Subpart A—[Heading Amended]

In the heading of Subpart A by changing the proper name "Whole Blood (Human)" to read "Whole Blood."

§ 640.1 [Amended]

2. In the heading and text of § 640.1 by changing the proper name "Whole Blood (Human)" to read "Whole Blood."

§ 640.2 [Amended]

3. In § 640.2(a) by changing the proper name "Whole Blood (Human)" to read "Whole Blood."

§ 640.3 [Amended]

4. In § 640.3 (a) through (f) by changing the proper name "Whole Blood (Human)" to read "Whole Blood."

§ 640.4 [Amended]

5. In § 640.4 (c) and (h) by changing the proper name "Whole Blood (Human)" to read "Whole Blood"; and in paragraph (i) by changing the items "Platelet Concentrate (Human)" and "Platelet Concentrate" to read "Platelets."

§ 640.5 [Amended]

6. In § 640.5 (a) through (e) by changing the proper name "Whole Blood (Human)" to read "Whole Blood"; and in paragraph (c) by changing the item "Anti-Rh (Anti-D) Typing Serum" to read "Anti-D Blood Grouping Serum."

§ 640.6 [Amended]

7. In the heading and in the introductory paragraph of § 640.6 by changing the proper name "Whole Blood (Human)" to read "Whole Blood"; and in paragraph (c) by changing the proper name "Whole Blood (Human), Modified" to read "Whole Blood Platelets and/or Cryoprecipitate Removed."

§ 640.7 [Amended]

8. In the introductory text of § 640.7(g) by changing "Whole Blood (Human), Modified" to read "Whole Blood Platelets and/or Cryoprecipitate Removed"; and in paragraph (g)(1) by changing the word "Modified" to read "Platelets and/or Cryoprecipitate Removed."

Subpart B—[Heading Amended]

9. In the heading of Subpart B by changing the proper name "Red Blood Cells (Human)" to read "Red Blood Cells."

§ 640.10 [Amended]

10. In the heading and text of § 640.10 by changing the proper name "Red Blood Cells (Human)" to read "Red Blood Cells."

§ 640.11 [Amended]

11. In § 640.11 by changing the proper name "Red Blood Cells (Human)" to read "Red Blood Cells."

§ 640.12 [Amended]

12. In § 640.12 by changing the proper name "Red Blood Cells (Human)" to read "Red Blood Cells."

§ 640.13 [Amended]

13. In § 640.13 by changing the proper name "Whole Blood (Human)" to read "Whole Blood."

§ 640.15 [Amended]

14. In § 640.15 by changing the proper name "Red Blood Cells (Human)" to read "Red Blood Cells."

§ 640.16 [Amended]

15. In § 640.16 by changing the proper name "Red Blood Cells (Human)" to read "Red Blood Cells."

§ 640.17 [Amended]

16. In § 640.17 by changing the proper name "Red Blood Cells (Human)" to read "Red Blood Cells"; and by changing the proper name "Red Blood Cells (Human), Frozen" to read "Red Blood Cells Frozen."

§ 640.18 [Amended]

17. In the introductory paragraph of § 640.18 by changing the proper name"Red Blood Cells (Human)" to read "Red Blood Cells"; in paragraph (a) by changing the proper name "Whole Blood (Human)" to read "Whole Blood"; in paragraph (b) by changing the proper names"Red Blood Cells (Human), Frozen " and "Red Blood Cells (Human), Deglycerolized" to read "Red Blood Cells Frozen" and "Red Blood Cells Deglycerolized"; and in paragraph (d) by changing the proper name "Whole Blood (Human)" to read "Whole Blood."

Subpart C—[Heading Amended]

18. In the heading of Subpart C by changing the proper name "Platelet Concentrate (Human)" to read "Platelets."

§ 640.20 [Amended]

19. In the heading of § 640.20 and in paragraphs (a) and (b) by changing the proper name "Platelet Concentrate (Human)" to read "Platelets."

§ 640.22 [Amended]

20. In § 640.22(a) by changing the proper name "Platelet Concentrate (Human)" to read "Platelets."

§ 640.23 [Amended]

21. In § 640.23(a) by changing the proper name "Platelet Concentrate (Human)" to read "Platelets."

§ 640.24 [Amended]

22. In § 640.24(a) and (e) by changing the proper name "Platelet Concentrate (Human)"to read "Platelets"; in paragraphs (b) and (d) by changing the name "platelet concentrate" to read "platelets"; and in pargraph (b) by changing the word "is" to read"are".

§ 640.25. [Amended]

23. In § 640.25(a), in the introductory text of (c) and in (c) (1) and (2) by changing the proper name "Platelet Concentrate (Human)" to read "Platelets."

Subpart D—[Heading Amended]

24. In the heading of Subpart D by changing the proper name "Single Donor Plasma (Human)" to read "Plasma."

§ 640.30 [Amended]

25. In the heading of § 640.30 and in paragraphs (a) and (b) by changing the proper names "Single donor Plasma (Human)" to read "Plasma" and in paragraph (b)(2) by changing the proper name "Whole Blood (Human)" to read "Whole Blood."

§ 640.32 [Amended]

26. In § 640.32(a) by changing the proper names "Single Donor Plasma (Human), Platelet Rich" to read "Plasma Platelet Rich"; "Single Donor Plasma (Human)" to read "Plasma"; "Single Donor Plasma (Human), Fresh Frozen" to read "Plasma Fresh Frozen"; and "Single Donor Plasma (Human), Liquid" to read "Plasma Liquid."

§ 640.33 [Amended]

27. In § 640.33(b) by changing the proper name "Single Donor Plasma (Human)" to read "Plasma."

§ 640.34 [Amended]

28. In § 640.34(a) by changing the proper names "Single Donor Plasma (Human)" to read "Plasma" and "Single Donor Plasma (Human), Liquid" to read "Plasma Liquid"; in paragrah (b) by changing the proper name "Single Donor Plasma (Human), Fresh Frozen" to read "Plasma Fresh Frozen"; in paragraph (c) by changing the proper name "Single Donor Plasma (Human), Liquid" to read "Plasma Liquid"; in paragraph (d) by changing the name "Single Donor Plasma (Human), Platelet Rich" to read "Plasma Platelet Rich"; in the introductory text of paragraph (e) by changing the proper name "Single Donor Plasma (Human)" to read "Plasma" and by changing the proper names "Platelet Concentrate (Human)" to read "Platelets", and "Cryoprecipitated Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF"; in paragraph (e)(1) by changing the proper names "Platelet Concentrate (Human)" to read "Platelets", and "Single Donor Plasma (Human), Fresh Frozen" to read "Plasma Fresh Frozen"; in paragraph (e)(2) by changing the proper names "Cryoprecipitated Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF", and "Single Donor Plasma (Human)" to read "Plasma"; in pargraph (e)(3) by changing the proper names "Platelet Concentrate (Human)" to read "Platelets", "Cryoprecipitated Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF", and "Single Donor Plasma (Human)" to read "Plasma"; and in paragraph (g)(2) by changing the proper names "Single Donor Plasma (Human), Platelet Rich" to read "Plasma Platelet Rich" and "Single Donor Plasma (Human), Liquid" to read "Plasma Liquid."

§ 640.35 [Amended]

29. In the introductory paragraph of § 640.35 by changing the proper name "Single Donor Plasma (Human)" to read "Plasma"; and in paragraph (s) by changing the proper name "Whole Blood (Human)" to read "Whole Blood."

Subpart F—[Heading Amended]

30. In the heading of Subpart F by changing the proper name "Cryoprecipitated Antihemophilic Factror (Human)" to read "Cryoprecipitated AHF."

§ 640.50 [Amended]

31. In the heading of § 640.50 and in paragraphs (a) and (b) by changing the proper name"Cryoprecipitated Antihemophilic Factor (Human)" to read"Cryoprecipitated AHF."

§ 640.52 [Amended]

32. In § 640.52(a) by changing the proper names"Cryoprecipitated Antihemophilic Factor (Human)" to read"Cryoprecipitated AHF" and "Platelet Concentrate (Human)" to read "Platelets."

§ 640.53 [Amended]

33. In § 640.53 (a) and (c) by changing the proper name "Cryoprecipitated

Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF."

§ 640.54 [Amended]

34. In § 640.54(a)(3), (b)(1), and (b)(3) by changing the proper name "Cryoprecipitated Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF."

§ 640.55 [Amended]

35. In § 640.55 by changing the proper name "Cryoprecipitated Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF".

§ 640.56 [Amended]

36. In § 640.56 paragraphs (a), (b), and (c)(1) by changing the proper name "Cryoprecipitated Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF."

Subpart G—[Heading Amended]

37. In the heading of Subpart G by changing the proper name "Source Plasma (Human" to read "Source Plasma."

§ 640.60 [Amended]

38. In the heading and text of § 640.60 by changing the proper name "Source Plasma (Human)" to read "Source Plasma."

§ 640.63 [Amended]

39. In § 640.63(a) by changing the proper name "Source Plasma (Human)" to read "Source Plasma."

§ 640.64 [Amended]

40. In the heading of § 640.64 and in paragraphs (a) and (c) by changing the proper name "Source Plasma (Human)" to read "Source Plasma."

§ 640.67 [Amended]

41. In § 640.67 by changing the proper name "Source Plasma (Human)" to read "Source Plasma."

§ 640.68 [Amended]

42. In § 640.68(a), (b) and (c) by changing the proper name "Source Plasma (Human)" to read "Source Plasma."

§ 640.69 [Amended]

43. In § 640.69(a), (b) and (c) by changing the proper name "Source Plasma (Human)" to read "Source Plasma."

§ 640.70 [Amended]

44. In the introductory text of § 640.70(a) by changing the proper name "Source Plasma (Human)" to read "Source Plasma" and in paragraph (b) by changing the proper names "Source Plasma (Human)" and "Source Plasma (Human), Salvaged" to read "Source Plasma" and "Source Plasma Salvaged", respectively.

§ 640.71 [Amended]

45. In § 604.71, in the introductory text of paragraphs (a) and (b), and paragraph (b)(1) and (2), by changing the proper name "Source Plasma (Human)" to read "Source Plasma."

§ 640.72 [Amended]

46. In § 640.72(a)(1) and (b) by changing the proper name "Source Plasma (Human)" to read "Source Plasma."

§ 640.74 [Amended]

47. In the heading of § 640.74 and in paragraph (a) by changing the proper name "Source Plasma (Human)" to read "Source Plasma" and in paragraph (b) by changing the proper name "Liquid Source Plasm (Human)" to read "Source Plasma Liquid."

§ 640.75 [Amended]

48. In § 640.75 by changing the proper name "Source Plasma (Human)" to read "Source Plasma."

§ 640.76 [Amended]

49. In § 640.76(a), (b), and (c) by changing the proper name "Source Plasma (Human)" to read "Source Plasma" and by changing the proper name "Source Plasma (Human), Salvaged" to read "Source Plasma Salvaged."

Subpart H—[Heading amended]

50. In the heading of Subpart H by changing the proper name "Normal Serum Albumin (Human)" to read "Albumin."

§ 640.80 [Amended]

51. In the heading of § 640.80 and in paragraph (a), introductory text of (b) and (b)(1) by changing the proper name "Normal Serum Albumin (Human)" to read "Albumin."

§ 640.81 [Amended]

52. In § 640.81 (e) and (g) by changing the proper name "Normal Serum Albumin (Human)" to read "Albumin."

§ 640.82 [Amended]

53. In § 640.82(f) by changing the proper name "Normal Serum Albumin (Human)" to read "Albumin."

§ 640.85 [Amended]

54. In the introductory paragraph of § 640.85 by changing the proper name "Normal Serum Albumin (Human)" to read "Albumin."

§ 640.86 [Amended]

55. In § 640.86 by changing the proper name "Normal Serum Albumin (Human)" to read "Albumin."

Subpart I—[Heading Amended]

56. In the heading of Subpart I by changing the proper name "Plasma Protein Fraction (Human)" to read "Plasma Protein Fraction."

§ 640.90 [Amended]

57. In the heading of § 640.90 and in paragraph (a), introductory text of (b), and (b)(1) by changing the proper name "Plasma Protein Fraction (Human)" to read "Plasma Protein Fraction."

§ 640.91 [Amended]

58. In § 640.91 (e) and (g) by changing the proper name "Plasma Protein Fraction (Human)" to read "Plasma Protein Fraction."

§ 640.92 [Amended]

59. In § 640.92(f) by changing the proper name "Plasma Protein Fraction (Human)" to read "Plasma Protein Fraction."

§ 640.95 [Amended]

60. In the introductory paragraph of § 640.95 by changing the proper name "Plasma Protein Fraction (Human)" to read "Plasma Protein Fraction."

§ 640.96 [Amended]

61. In § 640.96 by changing the proper name "Plasma Protein Fraction (Human)" to read "Plasma Protein Fraction."

Subpart J—[Heading amended]

62. In the heading of Subpart J by changing the proper name "Immune Serum Globulin (Human)" to read "Immune Globulin."

§ 640.100 [Amended]

63. In the heading of § 640.100 and in paragraphs (a) and (b) by changing the proper name "Immune Serum Globulin (Human)" to read "Immune Globulin."

§ 640.101 [Amended]

64. In § 640.101(e)(3) by changing the proper name "Measles Virus Vaccine, Live, Attenuated" to read "Measles Virus Vaccine Live"; and in paragraph (f) by changing the proper name "Immune Serum Globulin (Human)" to read "Immune Globulin."

§ 640.102 [Amended]

65. In the heading of § 640.102 and in paragraph (d) by changing the proper name "Immune Serum Globulin (Human)" to read "Immune Globulin."

§ 640.104 [Amended]

66. In § 640.104(b)(2) by changing the proper name "Measles Virus Vaccine, Live, Attenuaed" to read "Measles Virus Vaccine Live."

Subpart K—[Heading Amended]

67. In the heading of Subpart K by changing the proper name "Measles Immune Globulin (Human)" to read "Measles Immune Globulin."

§ 640.110 [Amended]

68. In the heading of § 640.110 and in paragraphs (a) and (b) by changing the proper name "Measles Immune Globulin (Human)" to read "Measles Immune Globulin."

§ 640.112 [Amended]

69. In the heading of § 640.112 and in paragraph (e) by changing the proper name "Measles Immune Globulin (Human)" to read "Measles Immune Globulin."

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

G. In Part 660:

§ 660.23 [Amended]

1. In § 660.23(a) by changing the proper name "Reagent Red Blood Cells (Human)" to read "Reagent Red Blood Cells."

2. In § 660.25 by revising paragraph (a)(5)(iii), to read as follows:

§ 660.25 Potency test without reference preparations.

(a) * * *

(5) * * *

(iii) For Anti-U, Anti-Kp^a, Anti-Kp^b, Anti-Js^a, Anti-Fy^b, Anti-N, Anti-Le^a, Anti-Le^b, Anti-Di^a, Anti-M^a, Anti-Jk^b, and Anti-Co^b, at least 2+ reaction with undiluted serum.

* * * * *

3. In § 660.28 by revising paragraph (d) to read as follows:

§ 660.28 Labeling.

* * * * *

(d) *Names of antibodies.*

Blood group designation for container label	Optional synonym for package label and package insert
Anti-A	None.
Anti-A$_1$	Do.
Anti-B	Do.
Anti-A,B	Do.
Anti-Di^a	(Anti-Diego^a)
Anti-Fy^a	(Anti-Duffy^a)
Anti-Fy^b	(Anti-Duffy^b)
Anti-I	None
Anti-Jk^a	(Anti-Kidd^a)
Anti-Jk^b	(Anti-Kidd^b).
Anti-K	(Anti-Kell).
Anti-k	(Anti-Cellano)
Anti-Kp^a	(Anti-Penney).
Anti-Kp^b	(Anti-Rautenberg).
Anti-Le^a	(Anti-Lewis^a–).
Anti-Le^b	(Anti-Lewis^b).
Anti-M	None.
Anti-N	Do.
Anti-M^v	(Anti-Gilfeather).
Anti-P$_1$	None.
Anti-D	(Anti-Rh$_o$).
Anti-CD	(Anti-Rh$_o$').
Anti-DE	(Anti-Rh$_o$'').
Anti-CDE	(Anti-Rh$_o$''').
Anti-C	(Anti-rh').
Anti-E	(Anti-rh'').
Anti-c	(Anti-hr').
Anti-e	(Anti-hr'').
Anti-C^w	(Anti-rh^w).
Anti-S	None.
Anti-s	Do.
Anti-U	Do.
Anti-Js^a	(Anti-Sutter).
Anti-Co^b	None.

Interested persons may, on or before December 30, 1980 submit to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Dockets Management Branch docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, as amended by Executive Order 12221, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Dockets Management Branch, Food and Drug Administration.

Dated: October 17, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–33509 Filed 10–30–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Parts 606 and 640

[Docket No. 80N–0120]

Current Good Manufacturing Practice for Blood and Blood Components; Uniform Blood Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) proposes to amend the biologics regulations by revising the labeling requirements for blood and blood components. The proposed revisions simplify and reduce the amount of information required on the container label. Machine-readable encodement of the critical information on the container label would be required. This document also announces the availability of a guideline describing the specifications for a uniform container label complying with the proposed rules. The proposed revisions and guideline were developed in response to the recommendations of the American Blood Commission's Committee for Commonality in Blood Banking Automation.

DATE: Comments by December 30, 1980. FDA proposes that any final regulation issued under this proposal be effective 1 year after the date of publication of the final regulation. The final regulation would apply to the labeling for all blood and blood components collected on or after the effective date.

ADDRESS: Written comments and requests for a single copy of the guideline to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Steven F. Falter, Bureau of Biologics (HFB–620), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301–443–1306.

SUPPLEMENTARY INFORMATION:

Introduction

In 1974, members of the private sector, including representatives of blood banks and the medical community, developed a long-term plan to implement the Department of Health and Human Services' (DHHS) National Blood Policy (NBP). This plan, the NBP, and related documents were published in the Federal Register of May 28, 1974 (39 FR 18614). Both the implementation plan and NBP set the regionalization of blood banks and transfusion services as a high priority to enhance regional and interregional resource-sharing and to more efficiently collect, process, distribute, and utilize a region's blood supply. Regionalization involves the increased centralization of blood collection and processing and consequent growth in the work-load of regional centers. These factors predispose toward the development and implementation of an automated data processing system to achieve rapid and accurate product distribution.

particularly for components such as platelets and granulocytes with dating periods measured in hours. To efficiently implement blood banking computerization, a nationally compatible system of encoding label information is necessary. The development of compatible equipment for the automation of blood banking requires the uniform placement of the encoded information, and, to assist in the gradual conversion to automation, the uniform placement of the analogous eye-readable information.

Blood and blood components are biological products subject to regulation under section 351 of the Public Health Service Act (42 U.S.C. 262) and are also drugs within the meaning of section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)). The products are governed by the applicable provisions of Parts 600 through 680) of the biologics regulations. Section 606.120 (21 CFR 606.120) prescribes the labeling requirements applicable to all licensed and unlicensed blood and blood component products. Part 640 (21 CFR Part 640) includes additional labeling requirements for specific blood products. Many blood establishments have printed custom labels which, while fully in compliance with the regulations, vary significantly in format and wording. This disparity in the wording and positioning of information, when considered in conjunction with the amount of information required on the container label, significantly decreases the readability of the label, and may be confusing to a user who is unfamiliar with an individual manufacturer's labels. Also, FDA and members of the private sector agree that the large amount of required information on the container label may obscure information that is absolutely necessary for the proper processing and administration of the product.

With extensive cooperation and support from the private sector, FDA has developed the revised labeling requirements now being proposed. FDA believes that the proposed regulations and the guideline now being made available will provide for the continued safe handling and administration of the products so labeled. In addition, the use of uniform labeling by all blood establishments will facilitate regional and interregional sharing of the Nation's blood supply, thereby promoting the efficient use of this valuable resource.

Background

In June 1974, the Committee for Commonality in Blood Banking Automation (CCBBA) was created with volunteers from all areas of the medical community with personnel from FDA participating. In 1975 the CCBBA was incorporated as a task force within the American Blood Commission (ABC). As part of its efforts, the task force undertook to: (1) Review the container label requirements for blood and blood components and recommend a revised simplified container label suitable for use by all blood establishements; (2) select the machine-readable code most serviceable for the blood service industry; and (3) select the key information for inclusion in both eye- and machine-readable form on the container label.

In its deliberations, the CCBBA recognized that an important benefit of simplified uniform labeling would be to decrease the incidence of human error due to the mislabeling or misreading of a blood product's container label, thereby decreasing the probability of an incompatible blood transfusion, a major danger in hemotherapy. Similarly, development of an automated data processing system would permit, at each step of the blood collection/administration process, computer confirmation of the information necessary for the safe and compatible transfusion of the product.

With these factors in mind, CCBBA created a prototype label. Samples of this label, modified to meet FDA regulations, were sent to 16 blood establishments for their use and comment. Revised final label recommendations were then presented to FDA for approval. The CCBBA kept the interested public informed of its progress by newsletter, lecture, and other media forms. Also, representatives presented their findings to the Bureau of Biologics advisory committee, the Panel on Review of Blood and Blood Derivatives. This proposal and the guideline being made available are based on CCBBA's recommendations as contained in its Final Report. Copies of CCBBA's Final Report, printed in seven volumes, are available from the American Blood Commission, 1901 North Ft. Meyer Drive, Suite 300, Arlington, VA 22209 and are also on file for public inspection with the Hearing Clerk, FDA.

Availability of Guideline

Members of the Nation's blood services complex are voluntarily participating in a program to convert from custom labels to a standardized container label format suitable for automated data processing. This format is intended for use by all blood establishments, licensed and unlicensed, in labeling blood and blood components. To assist in this conversion, the Bureau of Biologics at FDA is making available "Guidelines for the Uniform Labeling of Blood and Blood Components." This guideline describes in detail a standardized container label that is suitable for all blood and blood components intended for transfusion and that is in compliance with the revised labeling requirements proposed in this document. Instructions for the printing and use of the preferred bar-code system selected by CCBBA are described in the guideline. Standard ink colors are identified for use in printing the container label and other auxiliary labels, and for color coding the ABO blood group on the blood grouping portion of the container label.

FDA is encouraging voluntary compliance with the revised labeling requirements proposed in this document; therefore, the guideline may be used immediately in printing new standardized labels. However, the guideline may be revised at the time of publication of the final rule in response to comments received or any changes in the labeling requirements contained in the final rules. FDA urges that, by the effective date of the final rules, all establishments labeling blood and blood components convert to the standard label described in the final guideline. Instructions for obtaining a copy of the guideline and for the submission of comments are given at the end of this document.

The Proposed Rules

Throughout the remainder of this document, including the proposed rules, blood and blood products will be identified by their new proposed proper names. The new proper names are proposed elsewhere in this issue of the **Federal Register**, along with new proper names for other biological products. In many cases, such as for Whole Blood (Human), the proper name has been revised only by deleting the parenthetical word "Human"; however, for several products more extensive revisions to the proper names were proposed. For example, in this document, Whole Blood (Human), Modified is identified as "Whole Blood Platelets and/or Cryoprecipitate Removed"; Single Donor Plasma (Human) as "Plasma Frozen"; Single Donor Plasma (Human), liquid as "Plasma Liquid"; Platelet Concentrate (Human) as "Platelets"; and Cryoprecipitated Antihemophilic Factor (Human) as "Cryoprecipitated AHF."

In its review of the container label, the CCBBA task force evaluated each required label element to determine whether:

(a) It contributed to safety in the processing of the product, or

(b) Provided a necessary, immediate, and essential caution in the administration of the product.

Those elements meeting the above criteria are proposed for inclusion on the container label in § 606.121. The remaining elements will be either required in the instruction circular, as prescribed in proposed § 606.122, or omitted entirely if the information was determined to be obsolete, or not necessary for the proper use of the product.

Some new or revised elements are proposed for inclusion on the container label. As discussed earlier, the paramount objective of the CCBBA task force was to develop an automated data processing system serviceable to the blood banking community. Proposed § 606.121(c)(12) (i) through (v) prescribes the information the task force determined should be in both eye- and machine-readable form. The "collection center identifier" is based on the establishment's registration number, assigned by FDA. Space is reserved on the uniform container label for the inclusion of an encoded collection date, which may be useful for computerized facilities in inventory control. Because inexpensive on-site bar-code printers are not yet widely available, the encoding of the collection date will be optional. Although not required, establishments may encode information on the labels of blood or plasma products intended for further manufacturing use. Proposed § 606.121(c)(13) permits the submission of other encoding plans to the Director, Bureau of Biologics; however, the agency emphasizes that the full benefit of automated data processing is contingent on the nation-wide use of a uniform encoding system. FDA recognizes that rapid obsolescence is intrinsic in a developing technology such as automated data processing and will continue to review existing labeling procedures to ensure that blood product labeling requirements remain in step with modern technology.

In several cases, labeling requirements are being revised to reflect proposed amendments to the Whole Blood additional standards (21 CFR Part 640, Subpart A), published elsewhere in this issue of the **Federal Register**. A provision of that proposal would require that the blood of previously pregnant or transfused donors be tested to detect significant unexpected antibodies. Section 606.121(e)(1)(iii), (2)(ii), and (4) would require that any significant unexpected antibodies found be listed on the container labels of Whole Blood, Plasma and Red Blood Cells (except for the frozen, deglycerolized or washed Red Blood Cell products) prepared from that donor. Should no unexpected antibodies be found, this label element may be omitted.

Proposed § 606.121(c)(11) (i), (ii), and (iii) describe the criteria for labeling a product with the Rh group of the donor. As proposed, all blood and blood components intended for transfusion must be labeled with the Rh blood group. Previously, Rh group labeling was not required for Plasma and Cryoprecipitated AHF, because it was not generally considered essential for the safe transfusion of these products. On rare occasions when small amounts of red cell remnants are present, the transfusion of Rh positive Plasma to Rh negative persons has been reported to result in Rh allo-antibody production. Therefore, some clinicians believe that only Rh negative units should be used for transfusion patients, such as potentially child-bearing Rh negative females, for whom the consequinces of immunization are most serious. In addition, the uniform blood group labels described in the guideline include both ABO and Rh information on one label; therefore, it would be more burdensome for the user to delete the Rh portion than to include the Rh group which, under § 640.5(c) (21 CFR 640.5(c)), is already known for the donor. The wording of the provision is revised to reflect the revised Whole Blood standards which would require the testing of D-negative blood for the D^u antigen variant.

Proposed § 606.121(d)(1) would require a standard printing scheme for designating Rh positive and negative blood. The printing of the Rh positive and negative groups in contrasting forms will provide an additional safeguard against the mislabeling or misreading of this important information.

In proposed § 606.121(d)(2), a revised color scheme is prescribed for optional use in differentiating ABO blood groups. As noted by the CCBBA, the current color scheme does not correspond with the optional color scheme described for Blood Grouping Sera in § 660.28(a) (21 CFR 660.28(a)) and may be confusing to individuals handling both types of products. The proposed color scheme is more closely correlated to that used for Blood Grouping Sera. To forestall confusion, FDA is proposing in § 606.121(d)(3) that there be an interim transition period during which no color coding would be permitted. This will allow the introduction of the revised color codes without overlap or conflict with the color coding now in use. The transition period would be for 1 year beginning on the effective date of the final rules. The final rules would become effective 1 year after the date of publication in the **Federal Register**. Thus, the proposed color coding could be optionally introduced 2 years after the date of publication of the final rules in the **Federal Register**.

Proposed § 606.121(d)(4) would require that the colors used for the optional ABO group color coding be a visual match to specific color samples designated by the Director, Bureau of Biologics. The colors were selected from a coloring system readily available to printers. The colors are identical to the shades of blue and yellow previously selected for use in the Blood Grouping Serum color coding system. The coloring system and the selected colors are identified in the guidelines and in a separate memorandum filed under the docket number of this document and are available upon request from the Hearing Clerk, Food and Drug Administration. Colors in other coloring systems will be visually matched and identified upon request and submission of the coloring system to the Director, Bureau of Biologics.

The guideline describes a number of special labels recommended for use in simplying with the labeling requirements proposed under § 606.121 (f), (h) and (i) and for other purposes not addressed in the proposed regulations. For each special label described, the guideline recommends a specific color as an aid in identifying the type of special label being used. Under proposed § 606.121(d)(5), persons using color-coded special labels must either use the color coding system described in the guidelines or, prior to use, obtain the approval of the Director, Bureau of Biologics for the use of alternative color coding. By this means, FDA intends to prevent the use of color schemes conflicting with those described in the guidelines, and which may result in the misidentification on a special label.

Proposed § 606.121(h) prescribes the special labeling instructions for products shipped in an emergency situation, prior to completion of the required tests. This special label is revised from that previously required under § 640.7(f) (21 CFR 640.7(f)). In the proposed revisions to the Whole Blood standards, revised criteria are prescribed for the emergency shipment of blood, including a requirement that the shipping facility document in writing the circumstances necessitating the emergency shipment. Because this written record includes the name of the receiving facility, this information need no longer be on the container label. Previously, the

statements "Do not use until test results received from (name of licensee)" and "Perform crossmatch" were required on the special label for blood shipped in an emergency. In lieu of the former statement, the special label would include the results of any tests completed before shipment and an indication of those tests not completed before shipment. The wording is revised in recognition that the attending physician may determine that it is necessary to transfuse the blood before all test results are received. However, all tests results must be forwarded as soon as testing is completed. The statement "Perform Crossmatch" has been deleted as unnecessary because, under § 606.151(e) (21 CFR 606.151(e)), the receiving facility's standard operating procedure for compatibility testing must describe the procedures to expedite transfusions in life-threatening emergencies, including the procedures for performing a crossmatch.

The proposed revised Whole Blood standards permit the collection of blood for autologous use from patients failing to meet one or more donor suitability requirements, providing certain criteria are met. Proposed § 606.121(i) prescribes labeling which would differentiate blood collected from these patients, which is only suitable for autologous use, from blood collected from suitable donors for autologous purposes but which is equally suitable for homologous use. In the latter case, only a tie-tag or other special label need be used to identify the patient, date of collection, and the blood's intended autologous use. Blood from a patient failing to meet the donor suitability requirements or that is positive for hepatitis B surface antigen (HBsAg), must be permanently labeled on the final container with the statement "FOR AUTOLOGOUS USE ONLY" to preclude the erroneous use of the product for a homologous transfusion.

FDA advises that some of the provisions cross-referenced in proposed § 606.121(h) and (i) are being revised and redesignated in the proposed revised Whole Blood standards. Section 606.121(h) and (i) will be amended as appropriate in the final rules to reference the new, redesignated provisions.

For final products intended for transfusion, the information required for inclusion in the instruction circular is prescribed in proposed § 606.122. Many of the items proposed for this section were previously required on the container label, and per CCBBA's recommendations would now be required in the instruction circular. In addition, several new cautions or instructions to the user are proposed where the agency has determined that the additional information is necessary to insure that the products are used according to best current medical practice.

Although the requirements of this section are separated according to product, all the required information may be integrated into one common circular for use with all blood and blood component products. Such a circular has been jointly prepared by the American Association of Blood Banks and the American National Red Cross. This *Circular of Information for the Use of Human Blood and Blood Components* is approved for use by the agency and is becoming the voluntary, uniform standard for the blood service community.

Several other amendments are proposed for clarity and continuity. Revised § 606.120 contains only previously existent requirements concerning the general procedures for labeling blood and blood components. The sections of Part 640 pertaining to the labeling of blood and blood components are being deleted. Section 640.70, concerning the labeling requirements for Source Plasma, is being amended to exempt Source Plasma from the labeling requirements of this proposal.

Because this proposed rule represents a substantial revision from the labeling currently required, the agency proposes that any final regulation issued under this proposal be effective 1 year after the publication of the final regulation. The final regulation would apply to the labeling for all blood and blood components collected on or after the effective date.

FDA is permitting the immediate voluntary use of labels and instruction circulars complying with this proposed regulation except that the proposed ABO blood group color coding under § 606.121 (d)(3) may not be used until the specified effective date. The new container label is intended for use only in conjunction with a revised instruction circular meeting the requirements of proposed § 606.122. Therefore, the revised instruction circular must be available concurrent with the use of the new container label. Licensed establishments may begin using the new label without its prior review and approval by FDA, provided the label is printed in accordance with the specifications described in the guideline. Concurrent with its use, licensed establishments should submit the revised label and instruction circular to the Director, Bureau of Biologics as an amendment to their product license(s).

Pertinent background data on which the agency relies in proposing these amendments are on public display in the Dockets Management Branch, Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

The agency has determined that under proposed § 25.24(d)(13) (published December 11, 1979, 44 FR 71742), this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 501, 502, 701, 52 Stat. 1040–1042 as amended, 1049–1050 as amended, 1050–1051 as amended, 1055–1056 as amended (21 U.S.C. 321, 351, 352, 371)) and the Public Health Service Act (sec. 351, 361, 58 Stat. 702 as amended, 703 (42 U.S.C. 262, 264)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Parts 606 and 640 are amended as follows:

PART 606—CURRENT GOOD MANUFACTURING PRACTICES FOR BLOOD AND BLOOD COMPONENTS

1. In Part 606:

a. By revising § 606.120 to read as follows:

§ 606.120 Labeling, general requirements

(a) Labeling operations shall be separated physically or spatially from other operations in a manner adequate to prevent mixups.

(b) The labeling operation shall include the following labeling controls:

(1) Labels shall be held upon receipt, pending review and proofing against an approved final copy, to assure accuracy regarding identity, content, and conformity with the approved copy.

(2) Each type of label representing different products shall be stored and maintained in a manner to prevent mixups, and stocks of obsolete labels shall be destroyed.

(3) All necessary checks in labeling procedures shall be utilized to prevent errors in translating test results to container labels.

(c) All labeling shall be clear and legible.

b. By adding new §§ 606.121 and 606.122, to read as follows:

§ 606.121 Container Label.

(a) The following container label requirements are designed to facilitate the use of a uniform container label for blood and blood components (except Source Plasma) by all blood establishments. "Guidelines for the

Uniform Labeling of Blood and Blood Components" is available upon request from the office of the Hearing Clerk, Food and Drug Administration.

(b) The label provided by the collecting facility and the initial processing facility shall not be removed, altered, or obscured, except that the label may be altered to indicate the proper name and other required labeling information for the contents remaining in a container after blood components have been removed.

(c) The container label shall include the following information as well as other specialized information, as required in this section for specific products:

(1) The propoer name of the product in a prominent position.

(2) The name, address, and, if licensed, the license number of each manufacturer.

(3) The donor, pool, or lot number relating the unit to the donor.

(4) The expiration date, including the day and year, and, if applicable, the hour.

(5) The appropirate donor classification statement, "paid donor," or "volunteer donor," in no less prominence than the proper name of the product.

(i) A paid donor is a person who receives monetary payment for a blood donation.

(ii) A volunteer donor is a person who does not receive monetary payment for a blood donation.

(iii) Benefits, such as time off from work, membership in blood assurance programs, and cancellation of nonreplacement fees that are not readily convertible to cash, do not constitute monetary payment within the meaning of this paragraph.

(6) For Whole Blood, Plasma, Platelets, and partial units of Red Blood Cells, the volume of the product, accurate to within ±10 percent.

(7) The recommended storage temperature.

(8) If the product is intended for transfusion, the statements:

(i) "Caution: Federal law prohibits dispensing without prescription".

(ii) "See circular of information for indications, contraindications, cautions, and methods of infusion".

(iii) "Properly identify intended recipient".

(9) The statement: "This product may transmit the agent of hepatitis".

(10) The name and volume of source material, when applicable.

(11) The statement: "Caution: For Manufacturing Use Only", when applicable.

(12) If the product is intended for transfusion, the ABO and Rh groups of the donor shall be designated conspicuously. The Rh group shall be designated as follows:

(i) If the test using Anti-D Blood Grouping Serum is positive, the product shall b labeled: "Rh positive".

(ii) If the test using Anti-D Blood Grouping Serum is negative but the test for D^u is positive, the product shall labeled: "Rh positive".

(iii) if the test using Anti-D Blood Grouping Serum is negative and the test for D^u is negative, the product shall be labeled: "Rh negative".

(13) For products intended for transfusion, the container label shall bear encoded information in the form of machine-readable symbols approved for use by the Director, Bureau of Biologies. Machine-readable symnbols are optional for products intended only for further manufacturing use. The encoded information shall adequately identify the following:

(i) Proper name of the product.

(ii) Type of anticoagulant (for whole blood and red blood cell products only).

(iii) Collection center identifier.

(iv) Unit number.

(v) ABO and Rh blood group of the donor.

(d) The paper of the container label shall be white and print shall be solid black, with the following exceptions:

(1) The Rh blood group shall be printed as follows:

(i) Rh positive: Use black print on white background.

(ii) Rh negative: Use white print on black background.

(2) The name of the product, the donor classification statement, and the statement "properly identify intended recipient" shall be printed in solid red.

(3) On or before (2 years after date of publication of final rule in the **Federal Register**), a color scheme may not be used on the container label for differentiating ABO blood groups; after that date, the following color scheme may be used:

Blood group	Color of label paper
O	White.
A	Blue.
B	Yellow
AB	Green.

(4) Ink colors used for the optional color coding system described in paragraph (3) above shall be a visual match to specific color samples designated by the Director, Bureau of Biologics.

(5) Special labels, such as those described in paragraphs (h) and (i) of this section, may be color coded using the colors recommended in the guideline (see § 606.121(a)), or colors otherwise approved for use by the Director, Bureau of Biologics.

(e) Container label requirements for particular products or groups of products.

(1) Whole Blood labels shall include:

(i) The volume of anticoagulant.

(ii) The name of the applicable anticoagulant, immediately preceding and of no less prominence than the proper name and expressed as follows: (*a*) ACD, (*b*) CPD, (*c*) Heparin, or (*d*) CPDA–1.

(iii) If tests for unexpected antibodies are positive, blood intended for transfusion shall be labled: contains (*name of anitibody*).

(2) Red Blood Cells labels shall include:

(i) The volume and kind of Whole Blood, including the type of anticoagulant, from which the product was prepared.

(ii) It tests for inexpected antibodies are positive, Red Blood Cells intended for transfusion shall be labeled: contains (*name of anitibody*) (except that this requirement shall not apply to the frozen, deglycerolized, or washed Red Blood Cell products).

(3) Labels for Red Blood Cells Deglycerolized, Plasama Platelets, Granulocytes, and any product prepared in an open system shall bear the hour of expiration.

(4) If tests for unexpected antibodies are positive, Plasma intended for transfusion shall be labeled: contains (*name of anitibody*).

(5) Recovered plasma labels shall include:

(i) In lieu of an expiration date, the date of collection of the oldest material in the container.

(ii) The statement: "Caution: For Manufacturing Use Only" or "Caution: For Use in Manufacturing Noninjectable Products Only", as applicable.

(iii) For recovered plasma not meeting the requirements for manufacture into licensable products, the statement: "Not For Use in Products Subject to License Under Section 351 of the Public Health Service Act."

(f) Blood and blood components determined to be unsuitable for transfusion shall be prominently labeled: "NOT FOR TRANSFUSION", and the label shall state the reason the unit is considered unsuitable.

(g) Blood and blood components which are reactive for Hepatitis B Surface Antigen, but which are intended for further manufacturing, shall be labeled as required under § 610.40 of this chapter.

(h) The following additional information shall appear on the labeling for blood or blood components shipped in an emergency, prior to completion of required tests, in accordance with § 640.2(f) of this chapter.

(1) The following information shall appear on a special label or tie-tag attached to the container:

(i) The statement: "EMERGENCY USE ONLY."

(ii) Results of any tests prescribed under §§ 610.40 and 640.5(a), (b), or (c) of this chapter completed before shipment.

(iii) Indication of any tests prescribed under §§ 610.40 and 640.5(a), (b), or (c) of this chapter and not completed before shipment.

(2) The label may not bear the name or any other identification of the intended recipient.

(i) The following additional information shall appear on the labeling for Whole Blood or red Blood Cells intended for autologous infusion.

(1) The following information shall appear on a special label or tie-tag attached to the blood container:

(i) Information adequately identifying the patient. (e.g. name, blood group, hospital, identification no.)

(ii) Date of donation.

(iii) The statement: "FOR AUTOLOGOUS USE ONLY."

(2) Units of blood originally intended for autologous use, except those labeled as prescribed under paragraph (i)(3) of this section, may be issued for homologous transfusion provided the container label complies with all applicable provisions of § 606.121 (b) through (e). In such case, the special label or tie-tag required under paragraph (i)(1) of this section shall be removed.

(3) In place of the blood group label, each container of blood intended for autologous use and obtained from a donor who fails to meet any of the donor suitability requirements under § 640.3 of this chapter or who is reactive in the hepatitis tests prescribed under § 610.40 shall be prominently and permanently labeled: "FOR AUTOLOGOUS USE ONLY."

§ 606.122 Instruction circular.

An instruction circular shall be available for distribution if the product is not intended for further manufacturing. The instruction circular shall provide adequate directions for use, including the following information:

(a) Instructions to mix the product before use.

(b) Instructions to use a filter in the administration equipment.

(c) The statement "Do Not Add Medications" or an explanation concerning allowable additives.

(d) Known sensitizing substances.

(e) A description of the product, its source and preparation, including the name and proportion of the anticoagulant used in collecting the Whole Blood from which each product is prepared.

(f) Statements that the product was prepared from blood that was nonreactive when tested for hepatitis B surface antigen by an FDA required test and nonreactive when tested for syphilis by a serological test for syphilis (STS).

(g) The statements: "Warning. The risk of transmitting hepatitis is present. Careful donor selection and available laboratory tests do not eliminate the hazard".

(h) The names of cryoprotective agents and other additives that may still be present in the product.

(i) The names of all tests performed and results when necessary for safe and effective use.

(j) The use of the product, indications, contraindications, side effects and hazards, dosage and administration recommendations.

(k) For Whole Blood Platelets and/or Cryoprecipitate Removed, instructions not to use the unit of blood for patients requiring platelets or antihemophilic factor (whichever is applicable).

(l) For Red Blood Cells, the instruction circular shall contain:

(1) Instruction to add a suitable plasma volume expander if Red Blood Cells are substituted for Whole Blood.

(2) A warning not to add Lactated Ringer's Injection (U.S.P.) solution to Red Blood Cell products.

(m) For Platelets, the instruction circular shall contain:

(1) The approximate volume of plasma the Platelets were prepared from.

(2) Instructions to use as soon as possible but not more than 4 hours after entering the container.

(n) For Plasma, the instruction circular shall contain:

(1) A warning against further processing of the frozen product if there is evidence of breakage or thawing.

(2) Instructions to thaw the frozen product at a temperature between 30° and 37° C.

(3) When applicable, instructions to use the product within 6 hours after thawing.

(4) Instructions to administer to ABO group compatible recipients.

(5) A statement that this product has the same hepatitis risk as Whole Blood; other plasma volume expanders without this risk are available for treating hypovolemia.

(o) For Cryoprecipitated AHF, the instruction circular shall contain:

(1) The statement: "Average potency is 80 or more units of antihemophilic factor."

(2) The statement: "Usually contains at least 150 mg of fibrinogen"; or, alternatively, the average fibrinogen level determined by assay.

(3) A warning against further processing of the product if there is evidence of breakage or thawing.

(4) Instructions to thaw the product for 15 minutes at a temperature of 37° C.

(5) Instructions to store at room temperature after thawing and use as soon as possible but not more than 4 hours after entering or pooling and within 6 hours after thawing.

(6) A statement that saline is the preferred diluent.

(7) Adequate instructions for pooling to ensure complete removal of all concentrated material from each container.

(8) The statement: "Good patient management requires monitoring treatment responses to Cryoprecipitated AHF transfusions with periodic plasma factor VIII or fibrinogen assays in hemophilia A and hypofigrinogenemic recipients, respectively."

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

2. In Part 640:

§§ 640.7, 640.18, 640.26, 640.35 and 640.57 [Deleted]

a. Be deleting §§ 640.7, 640.18, 640.26, 640.35, and 640.57.

b. By revising the introductory text of § 640.70(a) to read as follows:

§ 640.70 Labeling.

(a) In addition to the labeling requirements of § 610.62 of this chapter, and in lieu of the requirements in §§ 606.121, 610.60, and 610.61 of this chapter, the following information shall appear on the label affixed to each container of Source Plasma:

* * * * *

The guideline is available for public examination between 9 a.m. and 4 p.m., Monday through Friday in the Dockets Management Branch (address below). Interested persons may obtain a single copy of the guideline by writing the Dockets Management Branch and identifying the document with the Dockets Management Branch document number found in brackets in the heading of the document.

Interested persons may, on or before December 30, 1980 submit to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA–305), Food

and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal and the guideline. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Dockets Management Branch docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, as amended by Executive Order 12221, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: October 17, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–33508 Filed 10–30–80; 8:45 am]

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21 CFR Part 640

[Docket No. 80N–0062]

Additional Standards for Human Blood and Blood Products; Reorganization and Revision of Regulations

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) proposes to amend the biologics regulations concerning Additional Standards for Human Blood and Blood Products by reorganizing and revising regulations on Whole Blood (Human). This action would organize these regulations into a logical sequence of manufacturing whole blood, from collection to issue, and would ensure that the criteria of safety, purity, potency, and efficacy applicable to Whole Blood (Human) are consistent with the best current judtment of the scientific community.

DATES: Comments by December 30, 1980. FDA proposes that any final regulation issued under this proposal be effective 30 days after the date of publication of the final regulation.

ADDRESS: Written comments to the Dockets Management Branch (Formerly the Hearing Clerk's office) (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Richard E. Fisher, Bureau of Biologics (HFB–620), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301–443–1306.

SUPPLEMENTARY INFORMATION: Whole Blood (Human) is a biological product subject to regulations under section 351 of the Public Health Service Act (42 U.S.C. 262). It is also a drug as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 321(g)(1)).Section 351 of the Public Health Service Act requires licensing of each manufacturer of Whole Blood (Human) before marketing the product in interstate commerce. Licenses for establishments manufacturing Whole Blood (Human) are issued only after the particular establishment has demonstrated it is capable of manufacturing Whole Blood (Human) that is safe, pure, potent, and effective. Establishment and product licensing for the production and distribution of Whole Blood (Human) is further governed by the Additional Standards for Human Blood and Blood Products under Part 640, Subpart A (21 CFR Part 640, Subpart A).

FDA has reviewed the existing regulations on Whole Blood (Human) in order to revise and update older standards of production and distribution. This review is consistent with the objectives of Executive Order 12044, "Improving Government Regulations." The agency proposes to revise and reorganize these regulations to reflect a logical sequence of manufacture, to delete outdated requirements, and to add new requirements based on recent scientific experience and developments. Because all blood establishments are required to comply with the standards of current good manufacturing practice (GMP) for blood and blood components under Part 606 (21 CFR Part 606), the requirements contained in the existing Whole Blood (Human) regulations and also prescribed in the GMP standards are deleted in the proposed standards for Whole Blood (Human). Changes in labeling requirements for Whole Blood (Human) are not being proposed at this time because the agency is proposing uniform labeling for blood and blood components in a proposal published elsewhere in this issue of the **Federal Register**. The current labeling requirements recodified as § 640.9a, will remain in effect pending final action on the proposal concerning uniform labeling for blood and blood components. In addition, a proposed new proper name for Whole Blood (Human), along with proposed new proper names for other biological products, is the subject of a proposal regarding changes in proper names of certain biological products published elsewhere in this issue of the **Federal Register**. The current proper name, Whole Blood (Human), is used throughout these proposed revisions of the Whole Blood (Human) regulations. The agency advises that new proper names that may be adopted under a final rule regarding the changes in proper names of certain biological products, will be included, as appropriate, in the final rule for revisions of the Whole Blood (Human) regulations.

Substantive changes of the existing Whole Blood (Human) regulations are as follows:

1. Proposed § 640.1 would expand the definition of Whole Blood (Human) to specify that Whole Blood (Human) is derived from a homan donor for transfusion or for use in further manufacturing.

2. Proposed § 640.2(a) would delete the term "licensed" in reference to "licensed blood establishments" because the additional standards for Whole Blood (Human) apply to both licensed and unlicended blood establishments under § 606.100.

3. Current § 640.2(b) would be deleted. The check on sterile technique is conducted to monitor the risk of environmental contamination and any subsequent growth of microorganisms during storage. However, because of technological advances and increased availability of equipment, virtually all blood banking establishments now use disposable plastic containers that do not require venting or entry, other than at the terminal end of integrally attached tubing for blood component separation. The use of disposable plastic containers eliminates the possibility of environmental contamination and the need for a continuing check on sterile technique. For these reasons and because of the requirement in proposed § 640.4(b) that all blood be collected in a closed system, FDA concludes that it is no longer necessary to require a periodic check on sterile technique on units of Whole Blood (Human). The current regulations on therapeutic bleedings are redesignated as § 640.2(b).

4. Current § 640.3(e) would be deleted. This section was promulgated before the source plasma regulation concerning the immunization of donors was published and when little was known about the possible effects that blood withdrawn from donors immunized to human blood cell antigens might have on the

recipient. In addition, this section does not take into consideration blood from immunized donors who fail to demonstrate a positive immune response to the injection of human blood cell antigens. The agency finds that this section is outdated because required laboratory tests ensure that blood withdrawn from donors immunized to human blood cell antigens will not affect the safety of transfusion.

5. Proposed § 640.3 would provide more specific guidance for determining the health of the donor to ensure continued safety during a blood donation. The agency proposes the following changes:

a. Proposed § 640.3(a) would require that a qualified licensed physician supervise the determination of donor suitability. The agency believes that the suitability of a blood donor must be determined by a physician who is licensed to practice medicine to ensure that adequate treatment is prescribed in the event of a serious donor reaction. Thus, this paragraph conforms with the Source Plasma (Human) donor suitability requirements under § 640.63(a).

b. Proposed § 640.3(b) would limit the ages of donors to 17 through 65 (up to 66th birthday). On or after the 66th birthday, a donor may be accepted only with the approval of the blood bank physician within 4 weeks before the date of donation, provided the donor has specific written consent from a licensed physician and meets all other criteria for donor acceptability. Donors who are considered minors under applicable local laws must have written consent as required by local law. The agency recognizes that the proposed age limitations are arbitrary; however, these proposed age limitations are based upon legal considerations and well-established correlations of the probability of cardiovascular disease as a function of increasing age.

c. Proposed § 640.3(c) would require that donors may not donate more than 450 milliliters ± 10 percent of Whole Blood (Human) in any 8-week period and not more often than four times per calendar year; unless, as an exception to this requirement, the donor is examined and certified in writing by a licensed physician to meet all other donor qualifications. The agency's review of published studies finds that the present limits concerning the frequency of blood donations does not protect blood donors from developing iron deficiency. These studies demonstrate that at the current permissible donation frequency, the donor's iron stores may not be replaced from the normal diet. Moreover, excluding donors on the basis of the lower limits of hemoglobin/hematocrit values for donor eligibility does not prevent donation by iron-depleted individuals because iron stores may be absent in individuals with acceptable hemoglobin/hematocrit values. The impact of a lower permissible freqency of blood donation on the nation's blood supply has been determined by a study conducted by FDA's Bureau of Biologics. Nineteen regions were surveyed, and these accounted for approximately 15 percent of the blood collected in the United States in 1976. Data from the survey demonstrate that with donations limited to four times per calendar year only 0.2 to 0.8 percent of the blood supply in these regions may be lost. Therefore, the agency concludes that limiting blood donations to 4 times per calendar year will adequately protect donors against iron depletion and will not significantly affect the blood supply needs of the nation.

d. Proposed § 640.3(d)(1) would require the use of venipuncture or fingerstick techniques to obtain blood for hemoglobin or hematocrit determination. Hemoglobin determinations must reflect venous hemoglobin values to prevent individuals with anemia or depleted iron stores from donating blood. The agency reviewed published studies concerning various sampling sites used for the source of blood for hemoglobin/hematocrit determination. These studies demonstrated that results obtained with earlobe puncture overestimate the hemoglobin/hematocrit values obtained by venipuncture or fingerstick techniques. Therefore, earlobe puncture screening may result in acceptance of a donor with anemia or depleted iron stores who would otherwise have been deferred. Furthermore, these studies demonstrate that venipuncture and fingerstick values are equivalent and more reproducible than earlobe puncture values. Based upon this evidence, the agency concludes that earlobe sampling is not suitable for hemoglobin/hematocrit determination.

The requirement for minimum hemoglobin values of not less than 12.5 grams of hemoglobin per deciliter of blood for females and 13.5 grams of hemoglobin per deciliter of blood for males is also proposed in this section. Acceptable hematocrit values, if substituted, are no less than 38 percent and 41 percent, respectively. The agency finds that the currently required minimum hemoglobin value of 12.5 grams of hemoglobin per deciliter of blood is significantly below the normal range for males. Large segments of the blood-banking community recognize this fact and commonly use a minimum hemoglobin value of 13.5 grams of hemoglobin per deciliter of blood or the equivalent hematocrit value of 41 percent for male donors. Consequently, the agency concludes that the current minimum hemoglobin/hematocrit value is below the physiologic norm for male donors.

e. Proposed § 640.3(d)(2) would provide specific criteria for blood pressure, pulse, temperature, and weight with a provision that donors outside these limits are acceptable if the donor is examined and certified in writing as acceptable by a licensed physician. The agency believes that specific criteria for donor screening are necessary to ensure continued donor health and the safety and efficacy of the blood product.

f. Proposed § 640.3(d)(3) would be revised to provide specific criteria for malaria, recent tooth extraction and other oral surgery, recent immunizations, and pregnancy. The agency believes that these criteria are necessary to adequately determine the medical history of the donor. Also, the agency is proposing two provisions, in addition to the current requirements concerning hepatitis, to further minimize the risk of transmitting hepatitis. First, a donor is premanently excluded if blood from that donor was the only unit of blood or blood component administered to a recipient who within 6 months developed posttransfusion hepatitis, and second, a donor is excluded if a tatto was received within 6 months prior to donation.

g. Proposed § 640.3(d)(4) would require the rejection of any donor suffering from symptoms of or receiving treatment for acute or chronic disease or receiving prescribed medication, with the exception of vitamins or contraceptives, unless a licensed physician approves otherwise. Also, by requiring the rejection of any donor who does not provide reliable answers to medical history questions because of the influence of drugs, alcohol, or for any other reason. The agency believes that these comprehensive requirements will further ensure an adequate determination of donor suitability.

6. Proposed § 640.4 would establish standards for blood containers and donor sets which will require that blood be collected in a closed system. For the reasons discussed in paragraph 3, above and because of the superiority of modern plastic equipment over glass containers in the collection, processing, storage, and distribution of blood, all blood-banking establishments shall be required to use approved plastic containers and donor sets exclusively.

Two additional provisions are also proposed in paragraphs (c) and (d) of this section to provide further assurance of a sterile and safe product. The first requires the collection of blood with a single venipuncture and the second requires the mixing of the blood unit by a method which results in a fully anticoagulated unit. Pilot and processing samples are also differentiated in paragraph (g) of this section to promote a clear understanding of their intended use.

7. Proposed § 640.5 would specify that laboratory tests be performed on either pilot or processing samples because both contain a representative sample of the donor's blood. Current § 640.5(a) is unchanged. The agency proposes the following changes:

a. Proposed § 640.5(b) would specify that: (1) the cell group must be determined by tests with anti-A and anti-B blood grouping serum; (2) the serum group must be determined by testing the donor's plasma or serum with known group A and group B red cells; and (3) the results of both cell and serum grouping must agree before a final label is placed on the blood container. The agency believes that a routine cell and serum test procedure will provide reliable ABO group determinations.

b. Proposed § 640.5(c) would require a test for the D varient (D^u) antigen on D negative blood to determine adequately the presence or absence of D antigen. Because the D antigen is recognized as the most immunogenic red cell antigen outside the ABO system, it is extremely important to accurately group blood donors to prevent problems in transfusion and pregnancy. To accurately determine whether a donor is a true Rh-negative individual, it is necessary to test for the D varient (D^u) antigen because donors with this phenotype are Rh-positive, and their blood to transfused to Rh-positive recipients. The agency believes that this provision will provide accurate confirmation of an Rh classification. In addition, the Wiener notations are deleted as concomitant nomenclature to the Fisher-Race notations in the Rh system. The agency believes that the Fisher-Race nomenclature is widely accepted in describing the main relationships of the Rh blood group system in simple and intelligible terms and is likely to remain indispensible to the scientific community. The Wiener nomenclature is deleted because of practical considerations and for no other reason.

c. Proposed § 640.5(d) would require a test for unexpected antibodies in previously pregnant or transfused donors. The agency believes that it is necessary to test these donors for unexpected antibodies to identify blood that may be harmful if transfused and blood that may confuse future serological evaluation. Other donors need not be tested because unexpected antibodies are rarely found in donors who have not been previously pregnant or transfused. Current § 640.5 (d) and (e) would be deleted.

8. Proposed § 640.6 would separate the storage conditions for blood into two categories, transit storage temperature and blood bank storage temperature. This section specifies that the transportation of blood from a collecting facility to a processing facility be either in a refrigerated environment capable of cooling the blood toward a temperature range of 1° to 10° C, or at a temperature range as close as possible to 20° to 24° C for a period not to exceed 4 hours. Also, for the reasons discussed in paragraph 10. below, this section further provides that blood for reissue need not be placed in temporary storage at 1° to 6° C provided the units are returned to the required refrigerated environment within 30 minutes.

9. Proposed § 640.7 would specify conditions for storage of blood used for component separation. These storage conditions reflect present practices in blood component separation. The current regulations on labeling are redesignated as § 640.9a.

10. A new § 640.8 is proposed and would specify the additional requirements concerning the issue and reissue of blood found in current §§ 640.5(e) and 640.4(i). The agency proposes the following changes:

a. Proposed § 640.8(a) would revise current § 640.5(e) and specify that blood may be issued or reissued if the container has a tamper proof seal which remains unbroken and is inspected visually prior to issue or reissue.

b. Proposed § 640.8(b) would revise current § 640.4(i) and specify that blood which has been moved from storage and exposed to room temperature for no more than 30 minutes would be permitted for reissue. Practical experience demonstrates that blood stored at 1° to 6° C and exposed to room temperature for no more than 30 minutes will not exceed 10° C. The agency would not require evidence of storage after issue because the integrity of the blood will not be compromised by this time period. The section would also extend the time period for use after a blood container has been entered from within 6 hours to within 24 hours. The agency has determined that this extended time period (24 hours) does not adversely affect the quality of Whole Blood (Human) because the significant growth of microorganisms during this short storage period at 1° to 6° C is unlikely.

11. A new § 640.9 is proposed and would incorporate exceptions to the requirements for the preparation of Whole Blood (Human) to better organize and consolidate the regulations. These exceptions concern the provisions for emergency issue, autologous infusion, pediatric use, and manufacturing use of Whole Blood (Human).

12. A new § 640.9a is proposed which is a redesignation of current § 640.7.

The agency proposes that the effective date of any final regulation issued under this proposal be 30 days after publication of the final regulation in the **Federal Register.**

Pertinent background data on which the agency relies in proposing these amendments are on public display in the Dockets Management Branch, Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

The agency has determined that under proposed § 25.24 (d)(10) (published on December 11, 1979 (44 FR 71742)), this proposal is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Therefore, under provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 701, 52 Stat. 1040–1042 as amended, 1050–1051 as amended, 1055–1056 as amended (21 U.S.C. 321, 352, 371)) and the Public Health Service Act (sec. 351, 58 Stat. 702, as amended (42 U.S.C. 262)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 640 be amended by revising Subpart A to comprise §§ 640.1–640.9a, to read as follows:

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

Subpart A—Whole Blood (Human)

Sec.

640.1 Whole Blood (Human).
640.2 General requirements.
640.3 Suitability of donor.
640.4 Collection of the blood.
640.5 Testing of the blood.
640.6 Storage of the blood.
640.7 Modification of Whole Blood (Human).
640.8 Issue and reissue of the blood.
640.9 Exceptions.
640.9a Labeling.

Subpart A—Whole Blood (Human)

§ 640.1 Whole Blood (Human).

Proper name and definition. The proper name of this product is Whole

Blood (Human). Whole Blood (Human) is defined as blood collected from a human donor for transfusion or for use in further manufacturing.

§ 640.2 General requirements.

(a) *Manufacturing responsibility.* A single establishment shall perform all manufacturing of Whole Blood (Human) including donor examination, blood collection, processing (except as provided in § 610.40(b)), storage, and issue except that the Director, Bureau of Biologics, may approve arrangements for divided manufacture between two or more licensed establishments which the Director determines are adequate to ensure compliance with the provisions of this subchapter.

(b) *Therapeutic bleedings.* Blood withdrawn to promote the health of a donor otherwise qualified under the provisions of this section, shall not be used as a source of Whole Blood (Human) unless the container label conspicuously indicate the donor's disease that necessitated withdrawal of blood.

§ 640.3 Suitability of donor.

(a) *Personnel.* The suitability of a donor as a source of Whole Blood (Human) shall be determined by a qualified licensed physician or persons under the physician's supervision and trained in determining donor suitability. Donor suitability shall be determined by medical history, limited physical examination, and hemoglobin or hematocrit evaluation on the day of and prior to the collection of blood from the donor. The establishment shall maintain on the premises a record which identifies the name and qualifications of the person immediately in charge of the employees who determines the suitability of donors when a physician is not present on the premises.

(b) *Age.* Donors shall be between the ages of 17 through 65 (up to the 66th birthday). Donors under 17 years of age are acceptable only if written consent to donate blood has been obtained in accordance with applicable local law. Donors are acceptable on or after the 66th birthday with the approval of the blood bank physician: *Provided,* That the donors have specific written consent from a licensed physician within 4 weeks before the date of donation and meet all other criteria for acceptability.

(c) *Volume and frequency of donation.* A donor shall not serve as a source of more than 450 milliliters ±10 percent of Whole Blood (Human) in an 8-week period and not more frequently than 4 times per calendar year, unless, as an exception to this requirement, the donor is examined by a licensed physician at the time of donation and certified in writing by the licensed physician to meet all other donor qualifications of this section.

(d) *Donor qualifications.* Donors shall be in good general health as determined in part by the following criteria:

(1) *Hemoglobin or hematocrit determination.* The hemoglobin shall be determined by using a sample of blood obtained by fingerstick or by venipuncture and shall be no less than 12.5 grams per deciliter of blood for females and 13.5 grams per deciliter of blood for males. Acceptable hematocrit values, if substituted, shall be no less than 38 percent and 41 percent, respectively.

(2) *Physical examination*—(i) *Blood pressure.* The systolic blood pressure shall be between 90 and 180 millimeters of mercury; the disastolic blood pressure shall be between 50 and 100 millimeters of mercury.

(ii) *Pulse.* The pulse rate shall be between 50 and 100 beats per minute and regular.

(iii) *Temperature.* The oral temperature shall not exceed 37.5° C.

(iv) *Weight.* Donors shall weigh at least 50 kilograms, except that donors weighing less may donate proportionately less in a reduced volume of anticoagulant if all other donor requirements are met.

(v) *Exceptions.* Donors with measurements outside the limits of paragraph (d)(2)(i) through (iv) of this section are acceptable if the donor is examined by a licensed physician and certified in writing by the physician to be acceptable.

(vi) *Donor skin.* The phlebotomy site shall be free of skin disease, and both arms shall be free of evidence of repeated skin punctures or scars indicative of drug addiction.

(3) *Medical history*—(i) *Viral hepatitis.* A donor shall be deferred permanently if blood from the donor was the only unit of blood or blood component administered to a patient who within 6 months developed posttransfusion hepatitis and who received no other blood fractions capable of hepatitis transmission; or if the donor is known previously to have been positive for Hepatitis B Surface Antigen (HBsAg); or if the donor has a history of viral hepatitis at any time. A donor shall be deferred if the donor has had, within 6 months prior to donation, close contact with an individual with viral hepatitis, or if the donor has been, within 6 months prior to donation, the recipient of blood products or a tattoo.

(ii) *Malaria.* A donor shall be deferred for a history of malaria exposure within 6 months following travel in an endemic area, within 3 years following residence in an endemic area, and malaria or antimalaria prophylaxis within 3 years prior to donation.

(iii) *Tooth extraction or oral surgery.* A donor shall be deferred for a history of tooth extraction or other oral surgery within 72 hours prior to donation.

(iv) *Immunization.* A donor shall be deferred until the symptons of immunization disappear, except that a symptom-free donor who has been immunized with measles (rubeola), mumps, yellow fever, oral polio vaccine, or animal serum products shall be deferred for 2 weeks after the last immunization; and with German measles (rubella), a donor shall be deferred for 1 month after the last injection.

(v) *Pregnancy.* A donor shall be deferred for known existing pregnancy and, unless a licensed physician approves otherwise, for 6 weeks postpartum.

(4) *General.* (i) A donor shall be deferred, unless a licensed physician approves otherwise, if the donor appears to be suffering from symptoms of or receiving treatment for acute or chronic disease or is receiving prescribed medication, with the exception of vitamins or contraceptives.

(ii) A donor shall be deferred if the donor appears to be under the influence of any drug or alcohol or who does not appear to be providing reliable answers to medical history questions.

§ 640.4 Collection of the blood.

(a) *Supervision.* A qualified licensed physician, or persons under the supervision of a qualified licensed physician trained in the procedure, shall draw blood from the donor. The establishment shall maintain on the premises a record that identifies the name and qualifications of the person immediately in charge of employees who collect blood when a physician is not present on the premises.

(b) *Prevention of contamination of the blood.* The skin of the donor at the site of phlebotomy shall be prepared by a method that gives assurance of a sterile container of blood. The blood shall be collected in a sterile, pyrogenfree, closed system.

(c) *Phlebotomy.* Blood shall be collected with a single venipuncture.

(d) *Mixing.* Blood shall be mixed by a method which gives a fully anticoagulated unit.

(e) *Blood containers.* Blood containers shall meet the following standards:

(1) The original blood container shall be the final container and shall not be entered for any purpose except for blood

transfusion or as specified elsewhere in this part.

(2) The blood container and anticoagulant shall meet specifications set forth in an approved new drug application filed pursuant to section 505 (a) and (b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 (a) and (b)) and Part 314 of this chapter.

(f) *Donor sets.* The donor set shall be an integral component of the blood container.

(g) *Test samples.* Pilot samples shall be contained in tubing integrally attached to the final container and shall be portions of the anitcoagulated blood contained in the final container. Processing samples shall be collected at the time of donation in separate containers or in tubing integrally attached to the final container.

§ 640.5 Testing of the blood.

All laboratory tests shall be performed on a pilot or processing sample of blood, and these tests shall include the following:

(a) *Serological test for syphilis.* Whole Blood (Human) shall be negative to a serological test for syphilis.

(b) *Determination of the ABO blood group.* Whole Blood (Human) shall be classified according to ABO blood group by testing the red blood cells with licensed Anti–A and Anti–B Blood Grouping Sera and by testing the serum or plasma with known group A and B cells. The unit of Whole Blood (Human) shall not be labeled unless the results of the two tests are in agreement. The testing facility may use unlicensed blood-grouping sera prepared at such facilities, if the blood grouping sera meet the potency and specificity requirements of Part 660 of this subchapter.

(c) *Determination of the Rh group.* Whole Blood (Human) shall be classified accoridng to Rh blood group by testing the red blood cells with licensed Anti-D Blood Grouping serum. If the test using Anti-D Blood Grouping Serum is positive, no further testing is required. If the the test using Anti-D Blood Grouping Serum is negative, the results shall be confirmed by further testing for D^U antigen using the antiglobulin technique of a technique of equivalent sensitivity. The testing facility may use unlicensed Anti-D Blood Grouping Serum and unlicensed Anti-Human Globulin Serum prepared at such facility, if the blood grouping sera meet the potency and specificity requirements of Part 600 of this subchapter.

(d) *Test for unexpected antibodies.* Whole Blood (Human) from previously pregnant or transfused donors shall be tested for unexpected antibodies by a method that demonstrates significant alloantibodies.

§ 640.6 Storage of the blood.

(a) *Blood bank storage temperature.* Immediately after collection, blood shall be stored at a temperature range between 1° to 6° C, except that blood from which platelets are to be removed shall be held in storage at a temperature between 20° to 24° C for a period not to exceed 4 hours from the time of collection.

(b) *Transit storage temperatures.* Blood that is transported from the collecting facility to the processing facility shall be transported in an environment capable of continuously cooling the blood toward a temperature range of 1° to 10° C; or at a temperature as close as possible to 20° to 24° C for a period not to exceed 4 hours. Blood transported from the storage facility shall be placed in an appropriate environment to maintain a temperature range between 1° to 10° C during shipment. Blood for reissue need not be placed in temporary storage at 1° to 6° C provided the units are returned to a controlled environment within 30 minutes.

§ 640.7 Modification of whole blood (human).

The establishment may remove platelets and cryoprecipitated antihemophilic factor from Whole Blood (Human) meeting the applicable requirements of this subchapter and the following conditions:

(a) *Platelets removed.* The blood from which platelets are to be prepared shall be stored in accordance with the provisions of § 640.6(a).

(b) *Cryoprecipitated antihemophilic factor removed.* The red blood cells shall be maintained between 1° and 6° C when the plasma is being frozen for removal of cryoprecipitated antihemophilic factor.

(c) *Cryoprecipitated antihemophilic factor and platelets removed.* Paragraphs (a) and (b) of this section shall apply until both platelets and cryoprecipitated antihemophilic factor are separated from the blood.

§ 640.8 Issue and reissue of the blood.

(a) Blood may be issued or reissued if the container has a tamper proof seal that remains unbroken and the blood is inspected visually prior to issue or reissue. The blood may not be issued or reissued if the color or physical appearance is abnormal or there is any indication or suspicion of microbial contamination.

(b) Blood may be reissued if the blood was continuously maintained at 1° to 6° C except during shipment or returned to storage at 1° to 6° C within 30 minutes after issue and if a pilot sample is properly attached. Blood lacking a pilot sample may be reissued if it is accompanied by instructions for sampling and for use within 24 hours after entering the container for sampling.

§ 640.9 Exceptions.

(a) *Emergency use.* Notwithstanding the provisions of § 610.1 of this chapter, blood may be issued before results of all of the tests prescribed in § 640.5 and the test for hepatitis B surface antigen prescribed in § 610.40(a) of this chapter have been completed, where such shipment is in response to a situation that demands immediate action as determined by a responsible person and documented in writing by the shipping facility. Tests shall be completed as soon as possible, and results shall be sent to the facility receiving the emergency shipment.

(b) *Autologous infusion.* Establishments may collect blood intended for infusion into the same person from whom it was collected even if the person fails to meet one or more of the provisions of § 640.3(b): *Provided,* That (1) the collecting facility has obtained a written request, including an explanation from the donor's physician of the desirability for autologous infusion and specifying the volume and frequency of collections; (2) the donor does not have and is not being treated for bacteremia; and (3) the hemoglobin is no less than 11 grams per deciliter of blood, or the hematocrit is no less than 34 percent, unless hemoglobin or hematocrit values below these limits are approved by the blood bank physician. Blood intended for autologous infusion shall be tested as required in § 640.5 except that the requirement that blood shall be negative to a serological test for syphilis in § 640.5(a) shall not apply. The requirement that blood shall be negative for hepatitis B surface antigen in § 610.40(d) shall not apply.

(c) *Pediatric use only.* The original blood container described in § 640.4 may be entered only once to transfer a portion of the blood from the original container to an approved empty container. The blood shall be used within 24 hours after entering the original container.

(d) *Further manufacturing use.* Sections 640.2(b), 640.4(e)(1), 640.5(b), (c), and (d), 640.6, 640.8, and paragraphs (a) and (b) of this section shall not apply to Whole Blood (Human) intended for further manufacturing use. Blood intended for further manufacturing use shall not be modified as described in § 640.7

§ 640.9a Labeling.

In addition to all other applicable labeling requirements, the following, except as prescribed in paragraphs (f), (g), and (h) of this section, shall appear on the label of each container:

(a) *Donor classification.* The appropriate donor classification statement prescribed in § 606.120(b)(2) of this chapter.

(b) *Anticoagulant*—(1) *Name.* The name of the anticoagulant immediately preceding and of no less prominence than the proper name, expressed as follows:

(i) Either "ACD," or "anticoagulant citrate dextrose solution";

(ii) Either "Heparinized" or "heparin solution";

(iii) Either "CPD" or "citrate phosphate dextrose solution";

(iv) Either "CPDA–1" or "anticoagulant citrate phosphate dextrose adenine solution (CPDA–1)."

(2) *Quantity.* The quantity and kind of anticoagulant used and the volume of blood.

(c) *Serological test and test for hepatitis B surface antigen.* Indication of the method used for serological test for syphilis and the test for hepatitis B surface antigen, and the results or the statements "Nonreactive for syphilis by STS" and "Nonreactive for HBsAg by FDA required test", respectively.

(d) *Blood group and type.* Designation of blood group and Rh factor:

(1) The blood group and Rh factor shall be designated conspicuously.

(2) If a color scheme for differentiating the ABO blood groups is used, the color used to designate each blood group on the container shall be:

Blood Group A: Yellow.
Blood Group B: Pink.
Blood Group O: Blue.
Blood Group AB: White.

(e) *Additional information for labels of Group O Bloods.* Each Group O blood shall be labeled with a statement indicating whether or not isoagglutinin titers of other tests to exclude so called "dangerous" Group O bloods were performed, and indicating the classification based on such tests.

(f) *Issue prior to determination of test results.* The label on each container of blood that is issued under § 640.9(a) concerning exceptions for emergency use shall bear the following information and instructions in lieu of the information specified in paragraphs (c), (d) and (e) of this section.

Emergency Shipment for Use Only by (Name of physician, hospital or other medical facility.)

CAUTION

Before Transfusion

1. Do not use until test results received from (name of licensee).
2. Perform crossmatch.

(g) *Whole Blood (Human), Modified.* The label on each container of blood that is issued pursuant to the provisions of § 640.7 shall bear, in addition to the other applicable labeling requirements, the following:

(1) Immediately following and in no less prominence than the proper name, the word "Modified."

(2) A prominent statement indicating that antihemophilic factor has been removed by cryoprecipitation. Such statement may appear on a separate label affixed to the container.

(3) Instructions not to use the unit of blood for patients requiring antihemophilic factor.

(h) *Whole Blood (Human) for further manufacturing use.* The label on each container of blood that is issued pursuant to the provisions of § 640.9(d) shall bear, in addition to the other applicable labeling requirements, the following statement: "Caution: For Manufacturing Use Only."

Interested persons may, on or before December 30, 1980 submit to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Dockets Management Branch docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, as amended by Executive Order 12221, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Dockets Management Branch, Food and Drug Administration.

Dated: October 17, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

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